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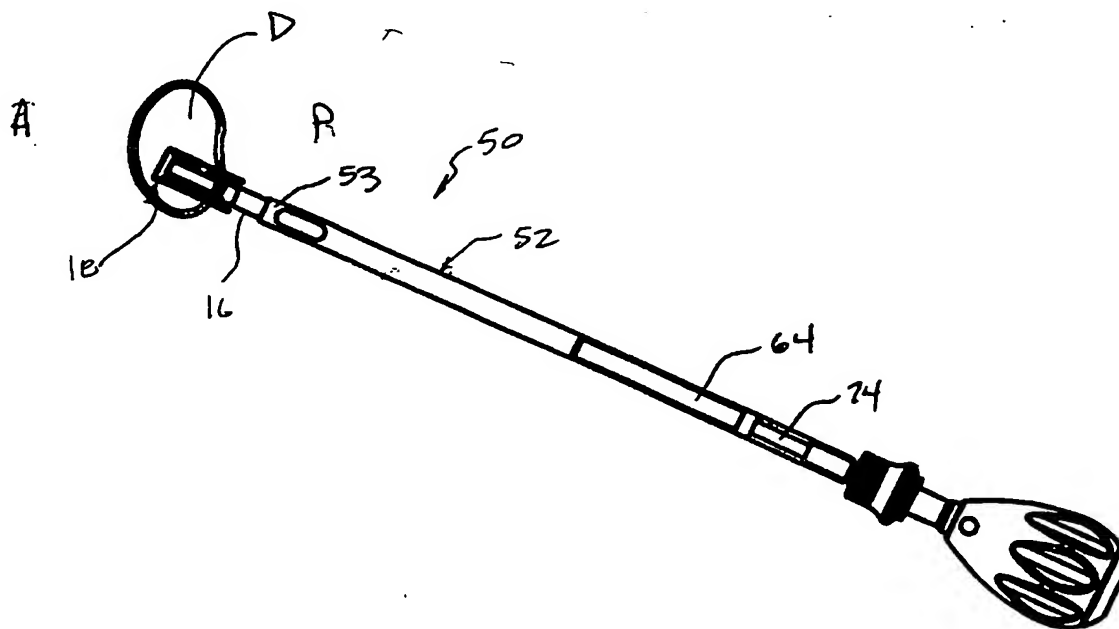
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(54) Title: METHODS AND INSTRUMENTS FOR INTERBODY SURGICAL TECHNIQUES



(57) Abstract: This invention relates to methods and instruments for performing a surgical procedure in a disc space between adjacent vertebrae. The instruments include a distractor (18) and a cutting instrument (52). In one embodiment the distractor includes a body portion (20) and a pair of flanges (26, 28) extending along opposite sides of the body portion (20) such that a slot (42, 44) is formed between the flanges (26, 28) and the body portion (20). The cutting instrument (52) is positionable over the body portion (20) and into the slots (42, 44) of the distractor (18) so that the flanges (26, 28) are positioned between the cutting instrument (52) and the adjacent tissue.

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METHODS AND INSTRUMENTS FOR INTERBODY SURGICAL TECHNIQUES

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Field of the Invention:

The present invention relates to spinal surgical techniques and instruments. More particularly, while aspects of the present invention may have other applications, the invention provides instruments and techniques suited for
10 interbody spinal surgery.

BACKGROUND OF THE INVENTION

Normally, intervertebral discs, which are located between endplates of adjacent vertebrae, stabilize the spine and distribute forces between the vertebrae
15 and cushion vertebral bodies. The discs may be displaced or damaged due to trauma, disease or aging. A herniated or ruptured annulus fibrosis may result in nerve damage, pain, numbness, muscle weakness, and even paralysis. Furthermore, as a result of the normal aging processes, discs dehydrate and harden, thereby reducing the disc space height and producing instability of the spine and
20 decreased mobility. Most typically surgical correction of a disc space includes a discectomy (surgical removal of a portion or the entire intervertebral disc.). The discectomy is often followed by preparation of the vertebral endplates to receive an implant, such as a fusion device. Fusion of the adjacent vertebrae is used to alleviate the pain associated with abnormal joint mechanics, premature
25 development of arthritis, and damage to the spinal structures.

Traditional surgical procedures for correction of spinal defects can cause significant trauma to the nerves and vasculature adjacent the spine. The potential for tissue trauma can be of particular concern when the surgical procedure dictates the use of a cutting instrument in the disc space in order to remove disc and bone
30 material to prepare the disc space for a fusion device, intervertebral spacer, or other

implant. In order to minimize the potential trauma, surgical procedures can require denervation and devascularization of tissue adjacent the disc space. Other procedures require manipulation of the nerves and vasculature in order to provide clear access to the disc space. While reducing the potential for contact with surgical instruments, manipulation and removal of the nerves and vasculature can still result in trauma and an increase the time and difficulty of the surgical procedure.

U.S. Patent No. 5,722,977 to Wilhelmy, incorporated herein by reference in its entirety, discloses a method and instrumentation for removal of a pair of rectangular blocks of vertebral bone tissue to provide an intervertebral recess. The instrumentation includes an intervertebral mortising cutter and a spacer that acts as a guide for the cutter. The procedure first requires the spacer to be inserted between the vertebral bodies. The cutter has a cutting head that defines a cavity that receives the spacer. In order to remove the bony material, the cutting head is pushed around the spacer and into the disc space. One disadvantage with the instrumentation disclosed in the '977 patent is that the cutting head is positioned between the spacer and the adjacent nerves and vasculature.

U.S. Patent No. 5,484,437 to Michelson discloses a technique and associated instrumentation for inserting a fusion device from a posterior surgical approach that provides protection for the surrounding tissues and neurological structures during the procedure. As described in more detail in the '437 patent, the surgical technique involves the use of a distractor having a penetrating portion that urges the vertebral bodies apart to facilitate the introduction of the necessary surgical instrumentation. The '437 patent also discloses a hollow sleeve having teeth at one end that are driven into the vertebrae adjacent the disc space created by the distractor. These teeth engage the vertebra to maintain the disc space height during subsequent steps of the procedure following removal of the distractor. In accordance with one aspect of the '437 patent, a drill is passed through the hollow sleeve to remove portions of the disc material and vertebral bone to produce a prepared bore for insertion of the fusion device. One disadvantage with this technique is that the procedure is performed through a sleeve, thus limiting working space and visibility of the surgeon. A further disadvantage is that the

height of the prepared disc space is limited by the spacing between penetrating portions of the distractor and the inner diameter of the sleeve.

While the more recent techniques and instrumentation represent an advance over earlier surgical procedures for the preparation of the disc space for insertion
5 of implants between the vertebrae, the need for improvement still remains. The present invention is directed to this need for improvement and provides convenient methods and instruments for safe and effective spinal surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to a spinal disc space distractor having a pair of flanges that protect adjacent tissue from a cutting instrument. The present invention is also directed to a spinal instrument assembly for distracting and
5 cutting a disc space to prepare the disc space for insertion of one or more implants therein. The present invention is further directed to surgical methods and procedures using the distractor and spinal instrument assembly.

In accordance with one aspect of the invention, a distractor is provided. The distractor includes a body portion extending between a leading end and a
10 trailing end. The body portion has an upper surface and an opposite lower surface, and opposite first and second sidewalls extending between the upper and lower surfaces. A first flange and a second flange extend from the leading end of the body portion towards its trailing end. The first and second flanges are spaced a distance from a respective one of the first and second sidewalls.

15 In accordance with a further aspect of the invention, a distractor is provided that includes a body portion extending between a leading end and a trailing end. The body portion has an upper surface and an opposite lower surface, and opposite first and second sidewalls extending between the upper and lower surfaces. The body portion includes a cavity formed therein that extends between the upper and
20 lower surfaces.

In accordance with another aspect of the invention, a spinal instrument assembly for distracting and cutting the disc space between adjacent vertebrae is provided. The assembly includes a distractor and a cutter. The distractor includes a body portion extending between a leading end and a trailing end. The body
25 portion includes opposite first and second sidewalls extending between the adjacent vertebral bodies. The distractor also includes a first flange and a second flange extending from the leading end towards the trailing end of the body portion. Each of the first and second flanges forms a slot along the body portion with a respective one of the first and second sidewalls. An elongated stem extends
30 proximally from the trailing end of the body portion. The cutter includes a cutting head at the distal end of a shaft. An upper member, a lower member, and a pair of sidewalls extending therebetween form the shaft and cutting head. A channel

extends through the cutting head and shaft. The channel is sized to receive the stem of distractor and to receive the body portion of the distractor such that the distal end of the sidewalls of the cutter are positionable in the slot and the body portion of the distractor is received in the channel.

5 According to a further aspect of the invention, a distractor is provided with an interfitting cutter having a channel sized to receive the distractor. The cutter has width that is less than the width of the distractor.

 According to another aspect of the invention, a method for preparing a disc space between adjacent vertebrae is provided. The method includes: accessing the
10 disc space through the skin and tissue of a patient; inserting a distractor into the disc space, the distractor having a body portion extending between a leading end and a trailing end, the distractor further including a first flange and a second flange extending from the leading end towards the trailing end of the body portion, each of the first and second flanges forming a slot along the body portion; and
15 positioning a cutting head over the body portion and into the slots.

 Further embodiments, forms, aspects, objects, features, benefits and advantages of the present invention shall become apparent from the detailed drawings and descriptions provided herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top plan view of a distractor assembly according to one aspect of the present invention.

FIG. 2 is an enlarged top plan view of the distal end portion of the distractor assembly of FIG. 1 and the distal end portion of a cutter.

FIG. 3 is a side elevational view of the distal end portion of the distractor and cutter of FIG. 2.

FIG. 4 is a perspective view of a distractor-cutter assembly according to a further aspect of the present invention.

FIGS. 4(a) and 4(b) are sectional views taken through lines 4(a)-4(a) and 4(b)-4(b), respectively, of FIG. 4.

FIG. 5 is the perspective view of the distractor-cutter assembly of FIG. 4 with a handle attached the proximal end of the cutter.

FIG. 6 is a cross-sectional view of an alternate embodiment distractor according to the present invention.

FIG. 7 is a cross-sectional view of another alternate embodiment distractor according to the present invention.

FIG. 8 is a top plan view of the distractor assembly of FIG. 1 with the distractor inserted into a disc space from a generally posterior approach.

FIG. 9 is a top plan view of the distractor-cutter assembly of FIG. 5 with the distractor in the disc space and the cutter adjacent the disc space.

FIG. 10 is the distractor-cutter assembly of FIG. 5 with the distractor and the cutter in the disc space.

FIG. 11 is an enlarged view of the distal end portion of the distractor and cutter in the disc space.

FIG. 12 is an enlarged top plan view of the distal end portion of another embodiment distractor and cutter according to the present invention.

FIG. 13 is a side elevational view of the distal end portion of the cutter of FIG. 12.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the present invention, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It will
5 nevertheless be understood that no limitation of the scope of the invention is intended thereby. Any alterations and further modification in the described processes, systems, or devices, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

10 The instruments and methods of the present invention have application to a wide range of surgical procedures, and particularly spinal procedures for preparing a disc space for insertion of an implant into the disc space. It is further contemplated that the surgical instruments and methods of the present invention have application in open surgical procedures and in minimally invasive surgical
15 procedures.

Referring now to FIG. 1, a distractor assembly 10 insertable into the disc space between adjacent upper and lower vertebrae is provided. Distractor assembly 10 includes a handle 12 connected to a proximal end of a stem 16 via handle coupling 14. A distractor 18 is secured to a distal end of stem 16. It is
20 contemplated that distractor 18 can be permanently affixed or removably attached to stem 16.

Referring now further to FIG. 2, distractor 18 includes a body portion 20 extending between leading end 22 and trailing end 24. Distractor 18 has a pair of opposite outermost sidewalls that are formed by a first flange 26 and a second
25 flange 28 secured to body portion 20 at leading end 22. Flanges 26, 28 extend from leading end 22 towards trailing end 24. It is preferred that flanges 26, 28 are integrally formed with body portion 20 at leading end 22. In the illustrated embodiment, a first end wall 46 extends between leading end 22 and first flange 26 and a second end wall 48 extends between leading end 22 and second flange 28.
30 However, flanges 26, 28 could also be removably attached to body portion 20.

Body portion 20 has first sidewall 30 and an opposite second sidewall 32. As shown in FIG. 3, each of the sidewalls 30, 32 extend towards the adjacent

vertebrae between an upper surface 34 and a lower surface 36 of body portion 20. Referring back to FIG. 2, a first slot 42 is formed between first flange 26 and first sidewall 30. A second slot 44 is formed between second flange 28 and second sidewall 32. Slots 42 and 44 have a width "d" sized to accommodate the distal end of a cutting instrument 52, as discussed further below.

Body portion 20 further includes a cavity 38 formed therethrough extending between upper surface 34 and lower surface 36. Body portion 20 has a height H1 between upper surface 34 and lower surface 36 that corresponds to the desired height for the distracted disc space. In the illustrated embodiment, the leading end portion of body portion 20 tapers to a reduced height H2 between upper surface 34 and lower surface 36 at leading end 22 to facilitate insertion of distractor 18 into the disc space. Preferably, flanges 26, 28 have a height that is equal to or is less than height H1 of body portion 20, and have a tapered portion that corresponds to the taper of body portion 20 towards leading end 22. The depth of insertion of distractor 18 into the disc space can be monitored under direct vision, with a viewing element inserted in the disc space, or via x-ray or fluoroscopic imaging of distractor 18.

Referring to FIGs. 2-5, according to a further aspect of the invention a cutting instrument or cutter 52 is provided that cooperates with and is interfittable with distractor 18 to form a spinal instrument assembly 50. Spinal instrument assembly 50 provides for distraction of the adjacent vertebrae and for cutting material from the disc space and/or the adjacent vertebrae to form an implant insertion location. Cutter 52 includes a shaft 64 and a cutting head 53 at the distal end of shaft 64. Shaft 64 includes a first sidewall 58 and an opposite sidewall 60. Sidewalls 58 and 60 are connected by an upper member 54 and an opposite lower member 56. Upper member 54 includes an upper cutting edge 54a at its distal end and lower member 56 includes a lower cutting edge 56a at its distal end. While the illustrated embodiment has shaft 64 with a square cross-sectional shape, other shapes are also contemplated, including, for example, a circular or rectangular cross-section.

Shaft 64 includes an interior channel 62 formed therethrough that opens at the distal end of cutter 52. As shown in FIG. 4(a), channel 62 has a distal first

portion 62a sized to receive stem 16 and body portion 20 of distractor assembly 10 with handle 12 removed from stem 16. Preferably, first portion 62a has a size slightly larger than body portion 20 and a shape approximating the shape of body portion 20. This provides a slip fit between body portion 20 and cutting head 53 that will guide cutting head 53 into the disc space and into the bony material of the adjacent vertebral bodies. Although the cross-section of the remaining proximal portion of channel 62 can have any shape, it is contemplated that the entire length of channel 62 has a shape that corresponds to the shape of first portion 62a.

Distractor 18 has an overall width W1 between the first flange 26 and second flange 28 that is greater the width W2 between the sidewalls 58, 60 of cutter 52. Distractor 18 thus ensures that when distractor 18 and cutter 52 are interfitted the flanges or outer-most sidewalls of distractor 18 are positioned adjacent the neural and vasculature tissue rather than the cutting edges of cutter 52.

In an alternate form shown in FIG. 4(b), channel 62 can be provided with a proximal second portion 62b that has a size slightly larger than stem 16 and a cross-sectional shape that approximates the outer surface of stem 16. This minimizes the relative movement between stem 16 and cutter 52 as cutter 52 is slidably advanced along stem 16.

In one alternate embodiment shown in FIG. 6, distractor 18' has a body portion 20' with a circular cross-sectional shape defined by first sidewall 30', opposite second sidewall 32', upper surface 34' and lower surface 36'. First flange 26' and second flange 28' each have a curved shape that parallels body portion 20', although vertically oriented flanges could also be provided. First slot 42' is formed between first flange 26' and sidewall 30' and second slot 44' is formed between second flange 28' and sidewall 32'. In this embodiment, a cutter would be provided with a circular opening at its distal end and a cross-sectional shape that allows rotation, either manually or other known power means, about body portion 20' to cut the adjacent vertebral endplates. Flanges 26' and 28' protect the adjacent tissue from the rotating cutting head. Alternatively, a non-rotating cutter could be used with distractor 18'.

In another alternate embodiment shown in FIG. 7, distractor 18'' has a first upper groove 21'' formed between upper surface 34'' and sidewall 30'' and a

second upper groove 23'' formed between upper surface 34'' and sidewall 32''. Distractor 18'' further has a first lower groove 25'' formed between lower surface 36'' and sidewall 30'' and a second lower groove 27'' formed between lower surface 36'' and sidewall 32''. The channel of cutter 52 can be configured to
5 interfit with these grooves, thus allowing the grooves to guide the cutting edges of the cutter into the disc space. First slot 42'' is formed between first flange 26'' and sidewall 30'', and second slot 44'' is formed between second flange 28'' and sidewall 32''. Grooves 21'', 23'', 25'', and 27'' resist upward and downward movement of the cutting blades with respect to distractor 18'' while flanges 26''
10 and 28'' protect the adjacent tissue from the cutting blade.

Referring back to FIGs. 2-5, upper member 54 includes an opening 68 and lower member 56 includes an opening 70 (FIG. 4(a)) identical to opening 68. These openings are substantially alignable with cavity 38 of distractor 18, and facilitate the removal of cut material from cavity 38 when the instrument assembly
15 is withdrawn from the disc space after cutting bony material. Cutter sidewall 60 includes a recess 72 formed therein, and cutter sidewall 58 includes a similarly shaped recess (not shown.) The recesses allow cutting edges 54a and 56a to be advanced beyond the leading end 22 of distractor 18. End walls 46, 48 prevent cutting head 53 from being advanced too far beyond leading end 22 of body
20 portion 20.

Sidewall 60 includes a window 80 to further provide visual observation and/or confirmation of the position of cutting head 53 with respect to distractor 18 by enabling viewing of depth markings on stem 16 of distractor assembly 10. Shaft 64 further includes an imaging probe 74 adjacent its proximal end to provide
25 image-guided control and monitoring of cutter 52. Further details regarding probe 74 are provided in U.S. Patent No. 6,021,343 to Foley et al., which is incorporated herein by reference in its entirety. Also contemplated are the use of x-ray and fluoroscopic imaging techniques to visualize cutting head 53 as it is inserted in the disc space.

30 Shaft 64 has a height H3 at its distal end that corresponds to the desired height of the prepared disc space into which the implant is to be inserted. It is contemplated that cutter 52 is inserted into the disc space with upper member 54

and lower member 56 parallel to the vertebral end plates and guided by body portion 20 of distractor 18. It is further contemplated that a number of cutters 52 of increasing height H3 may be provided and sequentially inserted over distractor 18 for removal of bony material from the vertebral endplates. While the illustrated
5 cutter 52 has flat cutting edges 54a, 56a, other shapes for the cutting edges are also contemplated. For example, rounded upper and lower cutting edges could be used to cut an arched path in the vertebral endplates. A standard coupling 76 is provided at the proximal end of cutter 52 for attachment to a cutter handle 78 to facilitate gripping and control of cutter 52. The proximal end of cutter 52 can also
10 be connected to or contacted by a driving tool, such as a slap hammer or the like to drive the cutting edges 54a, 56a into the bony material.

The steps of the spinal surgical procedure in accordance with one aspect of the present invention are depicted in FIGs. 8 – 11. In the depicted steps, there is illustrated a disc space D between adjacent vertebral bodies having a posterior side
15 P and an anterior side A. The skin and tissue are excised and disc space D is accessed using any known surgical technique and instruments. Typically, an opening is made in the disc annulus at the desired entry location, and all or part of the disc nucleus can be excised through this annulus opening. As shown in FIG. 8, distractor 18 of distractor assembly 10 is inserted into disc space D to distract disc
20 space to the desired height between the adjacent vertebrae. It is contemplated that, if necessary, the disc space can be sequentially distracted by known distractor instruments before insertion of distractor 18 or sequentially distracted by a number of distractors 18 of increasing height H1 until the desired disc space height is obtained.

25 When the desired distraction has been achieved, handle 12 is then removed from the proximal end of stem 16 and, as shown in FIG. 9, cutter 52 is slid over the proximal end of stem 16 to position cutting head 53 adjacent the disc space and distractor 18. As shown in FIGs. 10 and 11, cutter 52 is advanced over body portion 20 of distractor 18 so that the bony material of the vertebral endplates is cut
30 by cutting edges 54a and 56a. At least a portion of the cut material is deposited in cavity 38 of distractor 18. Cutter 52 forms a path or track for implant insertion while distractor 18 maintains disc space distraction. Flanges 26, 28 protect the

adjacent vasculature and nerves, such as dura S and nerve root N, as cutter 52 is advanced over and interfitted with body portion 20.

When the implant insertion path is cut to the desired depth into the vertebral endplates, distractor assembly 10 and cutter 52 can be removed from disc space D. The material in cavity 38 can be removed through openings 68, 70 of cutter 52 to facilitate disassembly of the instruments. Further cleaning and debris removal in disc space D can be completed if necessary before one or more implants are inserted into the disc space. The inserted implant may be any device suitable for insertion into the disc space. In one specific form, it is contemplated that an implant is inserted in the disc space in order to restore the disc height, restore segmental alignment and balance, and immobilize the unstable degenerated intervertebral disc area. The implant(s) may be conveniently implanted with any known instruments and tools, and any instrument that will firmly hold the implant and permit insertion in the disc space is contemplated. In one specific form, the implant is a fusion device such as a bone dowel, push-in implant, threaded implant or the like, that is advanced into the site prepared with the instruments of the present invention at the subject disc space. The inserted implant provides support of the adjacent vertebrae, and can be packed with bone growth material to facilitate fusion. Graft material may also be placed directly in the prepared bore in the disc space, either without any implant or packed around the inserted implant.

It is also contemplated that more than one implant can be inserted at bilateral locations in the disc space through either a single lateral or transforaminal approach to the disc space, or through multiple approaches taken with an anterior or posterior mid-line approach to the disc space. The inserted implants provide bilateral support of the adjacent vertebrae, and can be packed with bone growth material to facilitate fusion.

The instruments and methods have been disclosed with reference to a particular application for disc space preparation and implant insertion from an oblique, posterior approach to the spine. However, it will be understood that the instruments and methods may be utilized, or modified for use, for a variety of surgical applications and approaches including, but not limited to, a unilateral posterior approach, a lateral approach, other oblique approaches, and an anterior

approach. The instruments also have applications with laparoscopic or endoscopic procedures on the spine, such as, through the working channel cannula/endoscope described in U.S. Patent Application No Appl. Ser. No. 09/160,882 filed September 15, 1998, which is incorporated herein by reference in its entirety.

5 Referring now further to FIGs. 12-13, an alternate embodiment spinal instrument assembly having a cutter guided by a distractor will be described. Assembly 150 includes a distractor 118 having a body portion 120 extending between leading end 122 and trailing end 124. Body 120 is attached to stem 116 at trailing end 124. Distractor 118 has a pair of opposite outermost sidewalls 126,
10 128 formed by body portion 120. In one form, a slot 142 extends from position adjacent leading end 122 proximally through body portion 120 and stem 116. Slot 142 preferably extends substantially along the longitudinal center axis of distractor 118. An end wall 146 is formed between leading end 122 and slot 142.

Body portion 120 further includes a cavity 138 formed therethrough
15 extending between the upper and lower surfaces of body portion 120. Body portion has a height between the upper and lower surface that corresponds to the desired height for the distracted disc space. The leading end portion of body portion 120 can be tapered as discussed above with respect to distractor 18.

A cutting instrument or cutter 152 is provided that cooperates and interfits
20 with distractor 118 to form spinal instrument assembly 150. Cutter 152 includes a shaft 164 and a cutting head 153 at the distal end of shaft 164. Shaft 164 includes a first sidewall 158 and an opposite sidewall 160. Sidewalls 158 and 160 are connected by an upper member 154 and an opposite lower member 156. Upper member 154 includes an upper cutting edge 154a at its distal end and lower
25 member 156 includes a lower cutting edge 156a at its distal end. Upper member 154 includes an opening 168 and lower member 156 includes an opening (not shown) that are substantially alignable with cavity 138 of distractor 118, and facilitate the removal of cut material from cavity 138. Cutter sidewall 160 includes a recess 172 formed therein, and cutter sidewall 158 includes a similarly shaped
30 recess (not shown.)

Shaft 164 includes an interior channel 162 formed therethrough that opens at the distal end of cutter 152. Channel 162 is sized to receive stem 116 and body

portion 120 of distractor 118. This provides a slip fit between body portion 120 and cutting head 153 that will guide cutting head 153 into the disc space and into the bony material of the adjacent vertebral bodies. The sidewall recesses are sized and shaped to receive body portion 120 of distractor 118 and allow cutting edges 154a and 156a to be advanced beyond the leading end 122 of distractor 118. End wall 146 prevents cutting head 153 from being advanced too far beyond leading end 122.

Where a slot 142 is provided in distractor 118, a first guide pin 171 and a second guide pin 173 are positioned in channel 162. Guide pins 171, 173 extend between and are secured to upper member 154 and lower member 156. Guide pins 171, 173 are slidably received in guide slot 142. Cutter 152 can be advanced over body portion 120 with body portion 120 positioned in channel 162 and received in and extending laterally outwardly from sidewall recesses 172. Guide pins 171, 173 positioned in guide slot 142 prevent lateral deviation of cutting head 153 with respect to body portion 120 as cutter 152 is advanced over distractor 118. Pins 171, 173 further act as braces that stabilize and strengthen shaft 164 in the area of the sidewall recesses.

Distractor 118 has an overall width W1 between the first sidewall 126 and second sidewall 128 that is greater the width W2 between the sidewalls 158, 160 of cutter 152. Guide slot 142 and pins 171, 173 and the interfitted arrangement between distractor 118 and cutter 152 ensure that the sidewalls of distractor 118 are positioned adjacent to the neural and vasculature tissue rather than the cutting edges of cutter 152.

While the invention has been illustrated and described in detail in the drawings and the foregoing description, the same is considered to be illustrative and not restrictive in character. It is understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A distractor, comprising:
a body portion extending between a leading end and a trailing end, said
body portion including an upper surface and an opposite lower surface and
5 opposite first and second sidewalls extending between said upper and lower
surfaces; and
a first flange and a second flange each extending proximally from said
leading end of said body portion towards said trailing end, said first flange spaced
a distance from said first sidewall and said second flange spaced a distance from
10 said second sidewall.
2. The distractor of claim 1, further comprising an elongated stem
extending proximally from said trailing end of said body portion.
- 15 3. The distractor of claim 2, further comprising a handle removably
attached to a proximal end of said stem.
4. The distractor of claim 1, wherein said body portion includes a
cavity formed therein, said cavity extending between said upper surface and said
20 lower surface.
5. The distractor of claim 1, wherein said distractor includes a first end
wall extending between said trailing end of said body portion and said first flange
and a second end wall extending between said trailing end of said body portion and
25 said second flange.
6. The distractor of claim 1, wherein said first and second flanges are
integrally formed with said leading end of said body portion.
- 30 7. The distractor of claim 1, wherein said body portion has a height
between said upper and lower surfaces, said height being tapered along a part of
the length of said body portion such that said height is reduced at said leading end.

8. The distractor of claim 7, wherein said first and second flanges each have a height corresponding to said height of said body portion.

5 9. A distractor for distracting the disc space between adjacent vertebral bodies, comprising:

a body portion extending between a leading end and a trailing end, said body portion including opposite first and second sidewalls extending between the adjacent vertebral bodies; and

10 a first flange and a second flange each extending from said leading end towards said trailing end of said body portion, each of said first and second flanges forming with a respective one of said first and second sidewalls a slot along said body portion.

15 10. The distractor of claim 9, wherein said body portion includes an upper surface and a lower surface, each of said upper and lower surfaces contactable with a respective endplate of one of the adjacent vertebrae.

20 11. The distractor of claim 10, wherein said body portion has a height between said upper and lower surfaces, said height being tapered along a part of the length of said body portion such that said height is reduced at said leading end.

25 12. The distractor of claim 11, wherein said first and second flanges each have a height corresponding to said height of said body portion.

13. The distractor of claim 9, further comprising an elongated stem extending from said trailing end of said body portion.

30 14. The distractor of claim 9, wherein said body portion includes a cavity formed therein, said cavity extending between said upper surface and said lower surface.

15. The distractor of claim 9, wherein said first and second flanges are integrally formed with said leading end of said body portion.

16. A distractor, comprising:

5 a body portion extending between a leading end and a trailing end, said body portion including an upper surface and an opposite lower surface and opposite first and second sidewalls extending between said upper and lower surfaces, at least a portion of said upper and lower surfaces being contactable with the endplates of adjacent vertebral bodies when said body portion is inserted in the
10 disc space between the adjacent vertebral bodies, wherein said body portion includes a cavity formed therein extending between said upper surface and said lower surface.

17. The distractor of claim 16, further comprising a first flange and a
15 second flange extending from said leading end of said body portion towards said trailing end of said body portion, each of said first and second flanges forming with a respective one of said first and second sidewalls a slot along said body portion.

18. A spinal instrument assembly, comprising:

20 a distractor including:

a body portion extending between a leading end and a trailing end, said body portion including opposite first and second sidewalls extending between the adjacent vertebral bodies;

a first flange and a second flange each extending from said leading
25 end towards said trailing end of said body portion, each of said first and second flanges forming with a respective one of said first and second sidewalls a slot along said body portion;

an elongated stem extending proximally from said trailing end of said body portion; and

30 a cutting instrument including:

an elongated shaft having a distal cutting end, said shaft including an upper member, a lower member, and a pair of sidewalls extending

therebetween, said shaft defining a channel sized to receive said body portion of said distractor whereby said sidewalls are positionable in a respective one of said slots when said body portion of said distractor is in said channel of said shaft.

5 19. The assembly of claim 18, wherein each of said sidewalls of said shaft include a proximally extending recess formed therein at the distal end of said sidewall.

 20. The assembly of claim 18, wherein:
10 said upper member includes a cutting edge formed at the distal end of said upper member; and
 said lower member includes a cutting edge formed at the distal end of said lower member.

15 21. The assembly of claim 18, wherein:
 said body portion of said distractor includes a cavity formed therethrough extending between an upper surface and a lower surface of said body portion; and
 said upper member and said lower member of said shaft each define an opening therethrough in communication with said channel and alignable with said
20 cavity.

 22. The assembly of claim 18, wherein said distractor includes a first end wall extending between said leading end of said body portion and said first flange and a second end wall extending between said leading end of said body
25 portion and said second flange.

 23. The assembly of claim 18, wherein said shaft includes a probe for image guided navigation of said cutting head.

30 24. The assembly of claim 23, wherein said shaft includes a coupling member at a proximal end of said shaft for attachment of a handle thereto.

25. The assembly of claim 18, wherein at least one of said sidewalls of said shaft defines a window in communication with said channel.

5 26. A method for preparing a disc space between adjacent vertebrae, comprising:

accessing the disc space through the skin and tissue of a patient;

inserting a distractor into the disc space, the distractor having a body portion extending between a leading end and a trailing end, the distractor further
10 including a first flange and a second flange extending from said leading end towards said trailing end of said body portion, each of said first and second flanges forming a slot along said body portion; and

positioning a cutter over the body portion and into the slots formed between the body portion and the first and second flanges of the distractor.

15

27. The method according to claim 26, wherein positioning the cutter includes cutting bony material from the adjacent vertebral endplates to form an implant insertion location in the disc space.

20 28. The method according to claim 27, further comprising depositing at least a portion of the cut bony material into a cavity formed in the body portion of the distractor.

29. The method according to claim 27, further comprising inserting an
25 implant in the implant insertion location.

30. A spinal instrument assembly, comprising:
a distractor including a body portion extending between a leading end and a trailing end, said body portion including opposite first and second sidewalls
30 extending between the adjacent vertebral bodies and having a first width between said sidewalls;

a cutting instrument including an elongated shaft having a distal cutting end, said distal cutting end of said shaft configured to interfit with said distractor and having a channel with a height sized to receive said body portion of said distractor, said distal cutting end having a second width that is less than said first width.

31. The assembly of claim 30, wherein said distractor includes:
a first flange and a second flange each extending from said leading end towards said trailing end of said body portion, each of said first and second flanges forming with a respective one of said first and second body portion sidewalls a slot along said body portion; and
an elongated stem extending proximally from said trailing end of said body portion.

32. The assembly of claim 31, whereby said distal cutting end of said cutting instrument is positionable in a respective one of said slots when said body portion of said distractor is in said channel of said shaft.

33. The assembly of claim 32, wherein said distractor includes a first end wall extending between said leading end of said body portion and said first flange and a second end wall extending between said leading end of said body portion and said second flange.

34. The assembly of claim 30, wherein said distal cutting end includes opposite proximally extending recesses sized to receive said body portion of said distractor.

35. The assembly of claim 30, wherein said distal cutting end includes an upper member having a cutting edge formed at the distal end of said upper member and a lower member including a cutting edge formed at the distal end of said lower member.

36. The assembly of claim 30, wherein:

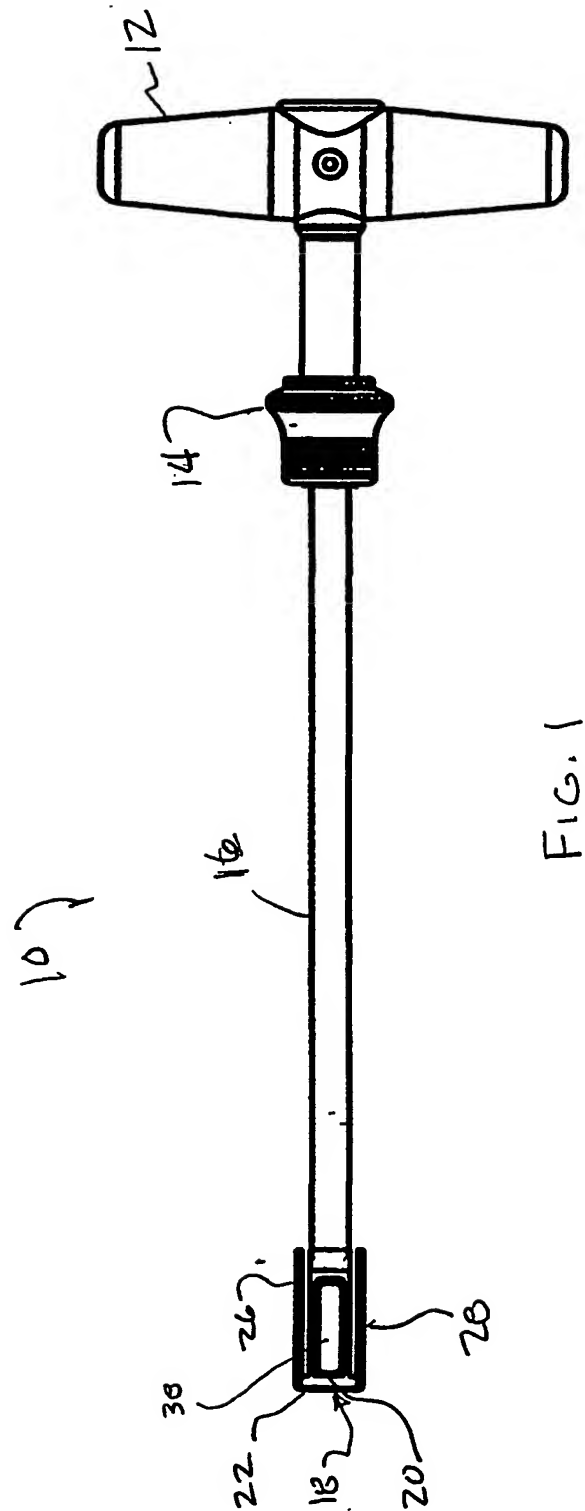
said body portion of said distractor includes a cavity formed therethrough extending between an upper surface and a lower surface of said body portion; and

said shaft defines an opening therethrough in communication with said
5 channel and alignable with said cavity.

37. The assembly of claim 30, wherein:

said body portion of said distractor includes a guide slot formed
therethrough extending generally parallel with said sidewalls of said body portion;
10 and

said cutting instrument includes at least one guide pin in said channel of
said shaft, wherein said guide pin is slidably received in said guide slot.



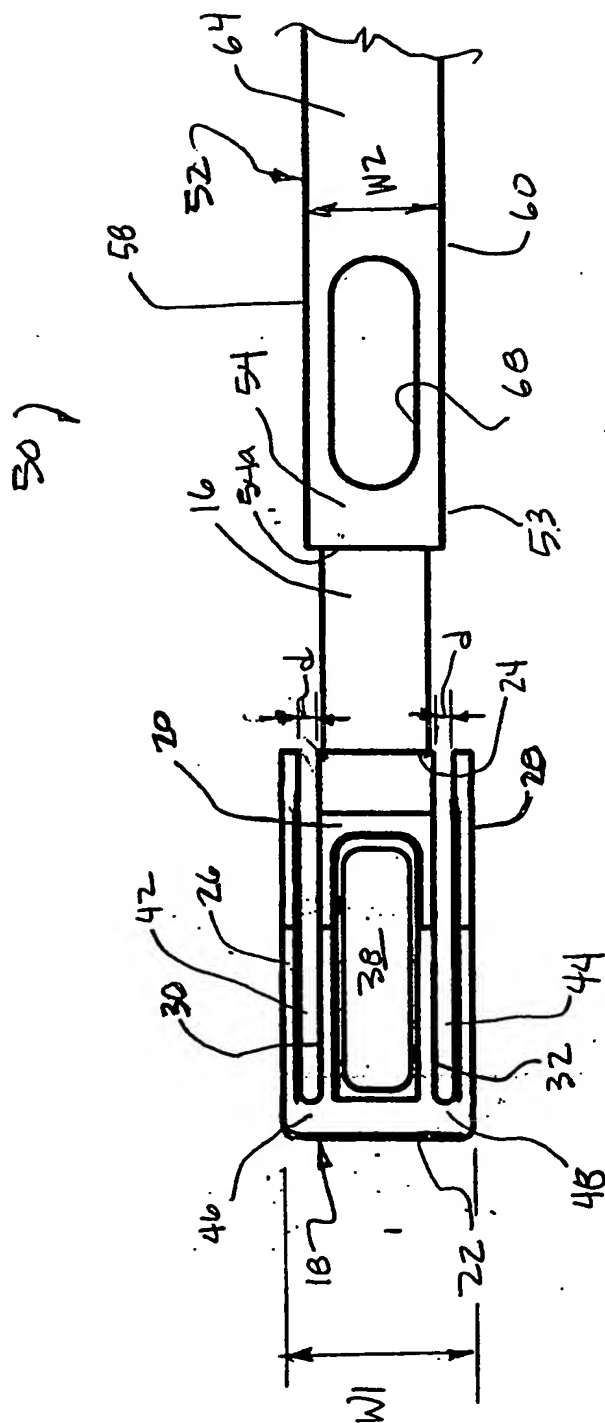


FIG. 2

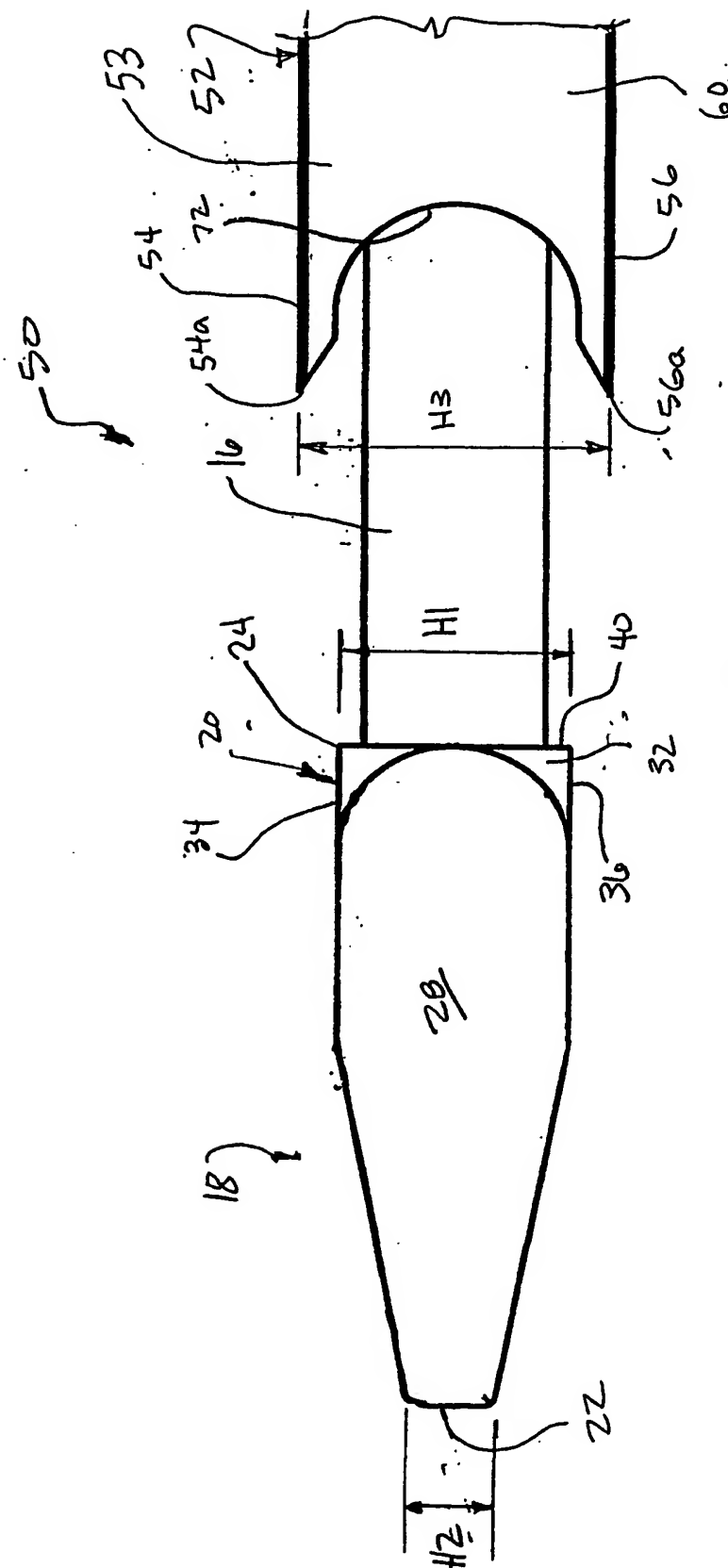


Fig. 2

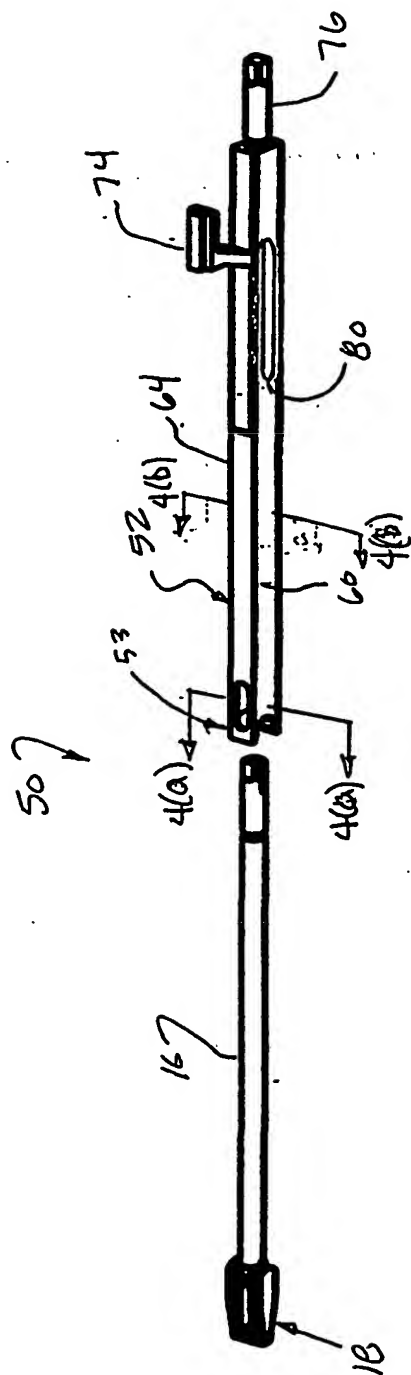


FIG. 4

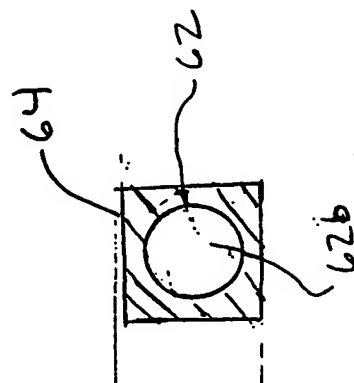


FIG. 4(b)

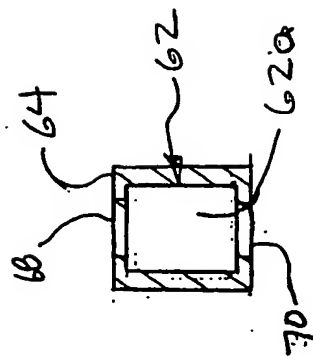
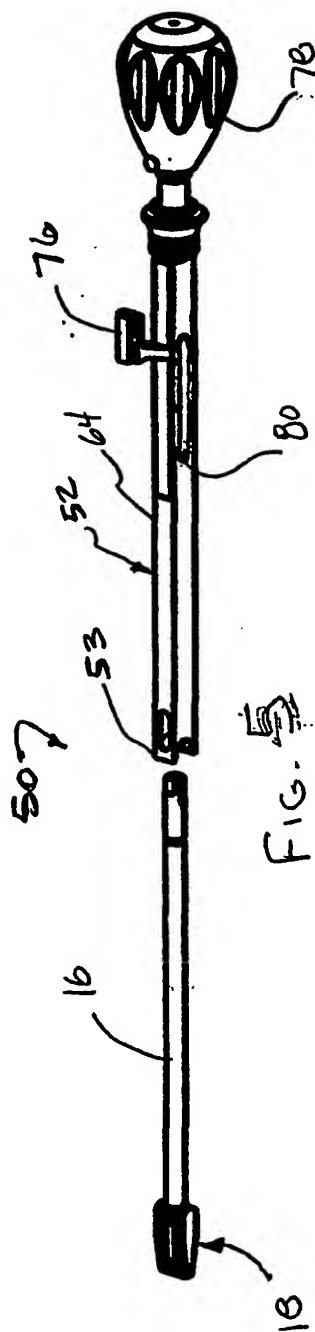


FIG. 4(a)



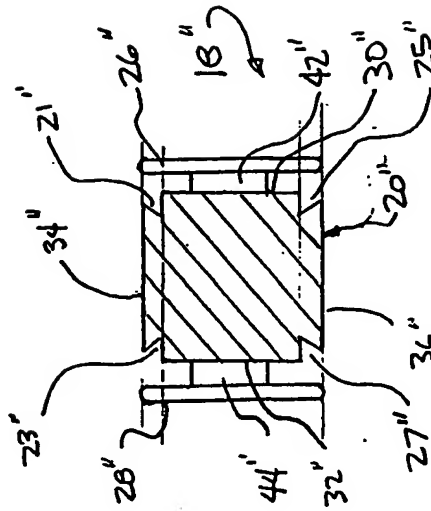


FIG. 7

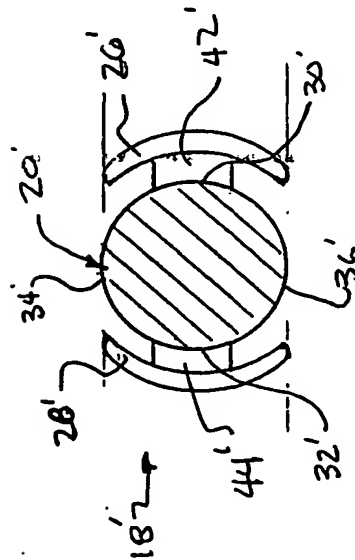
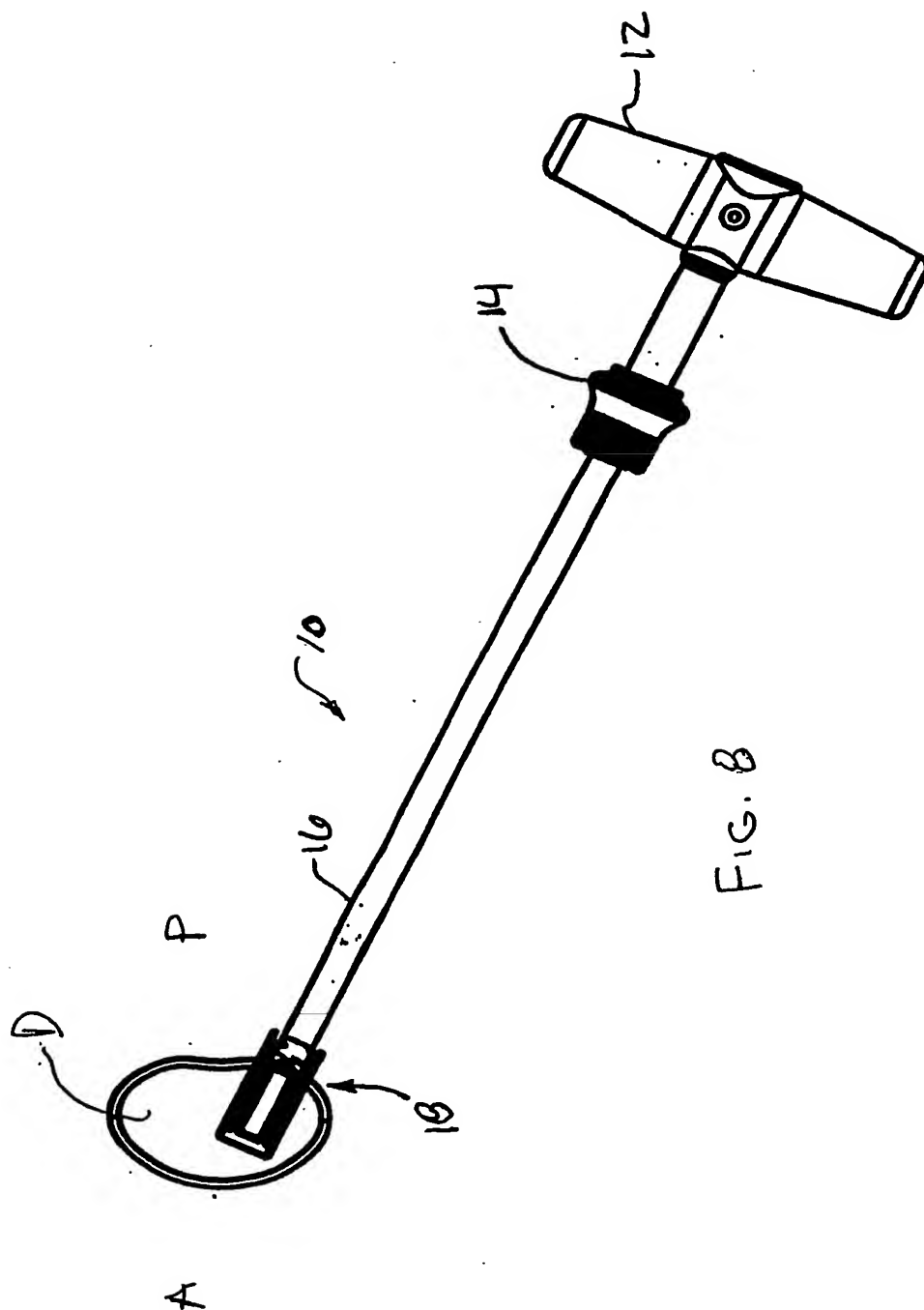
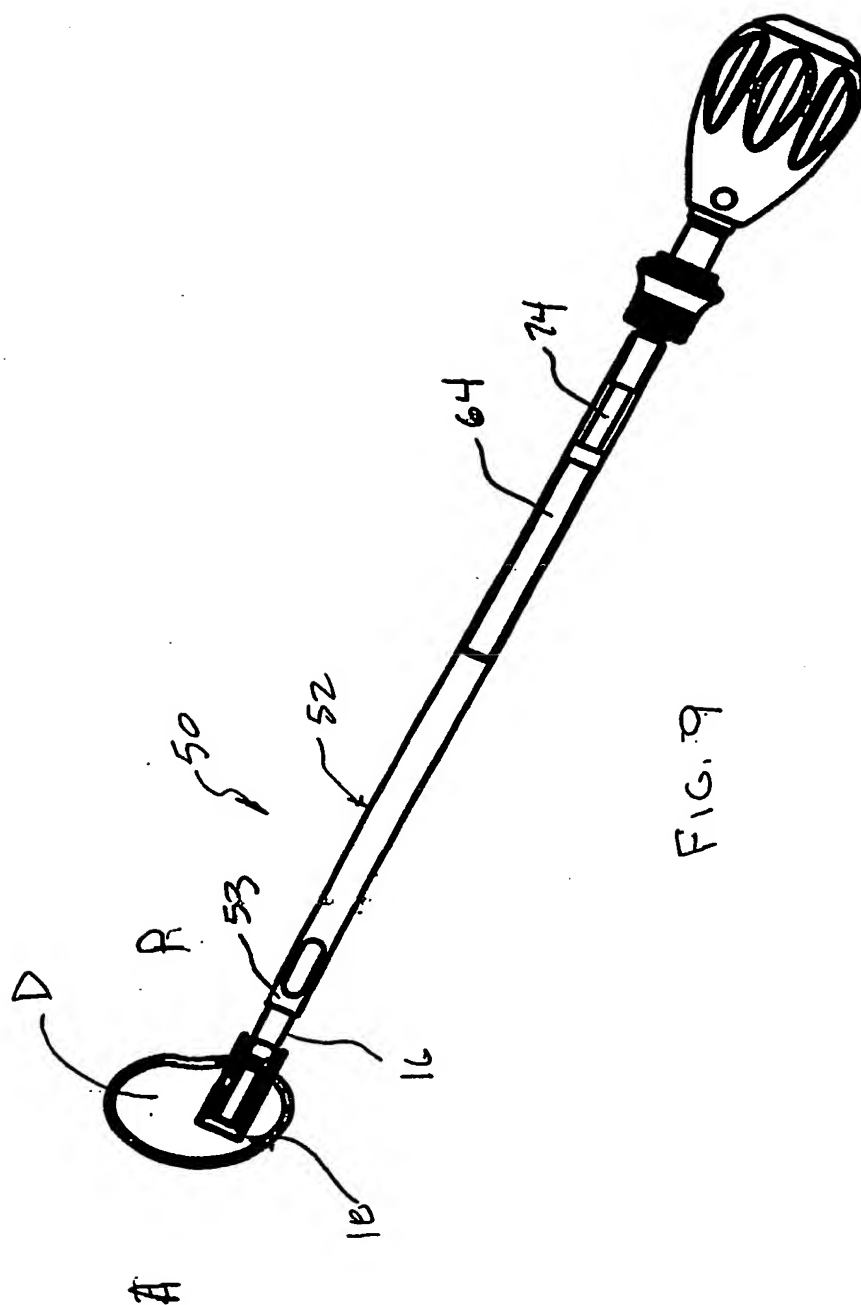


FIG. 6





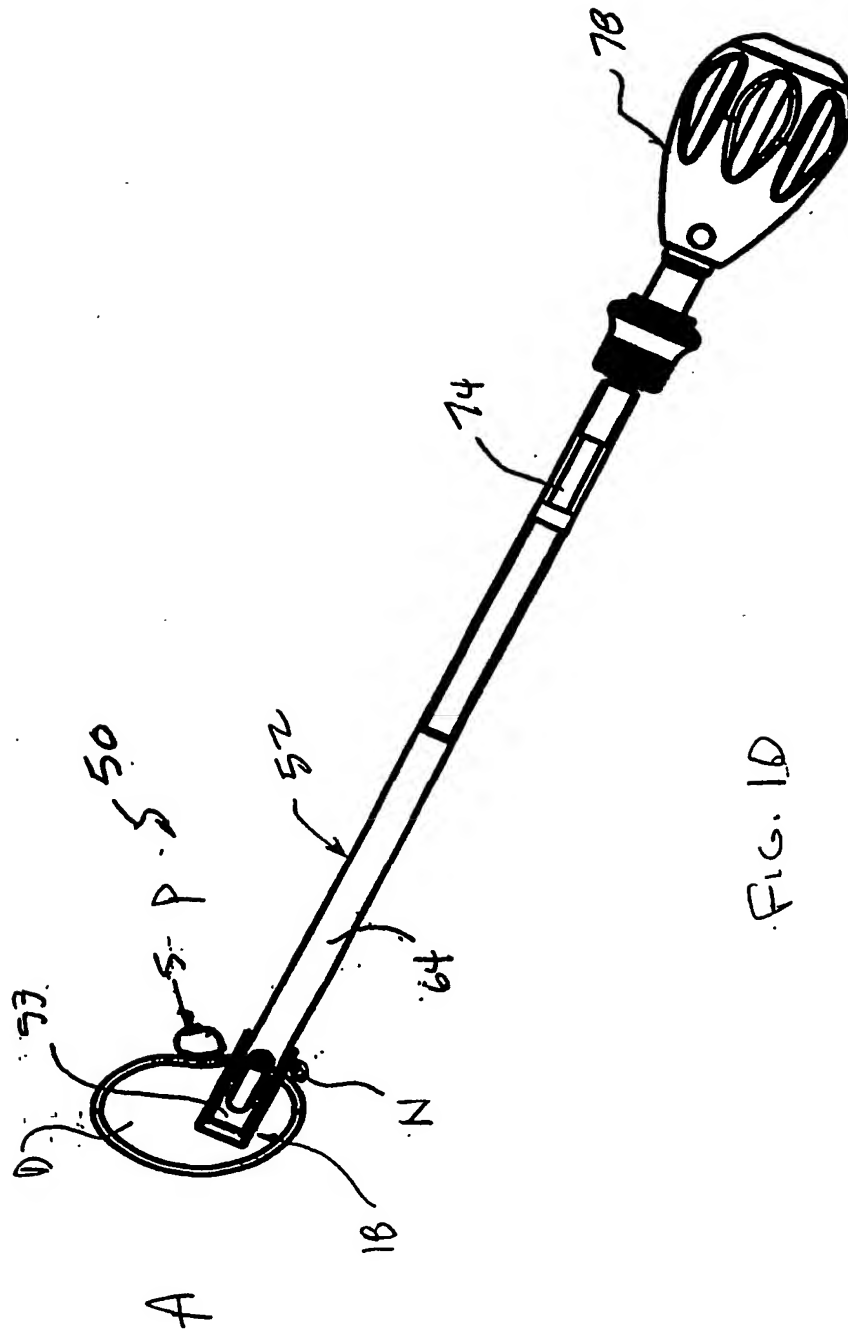
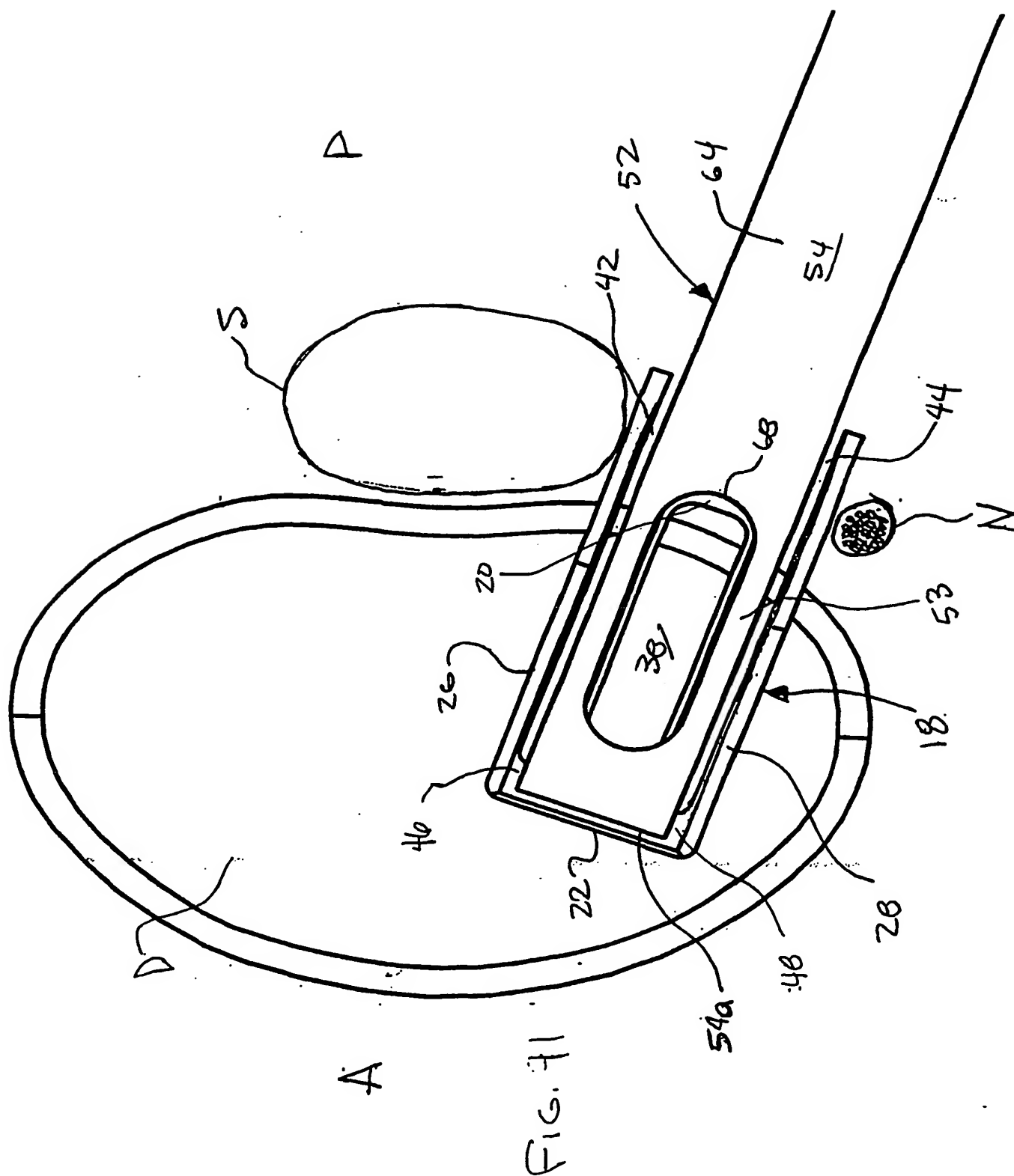
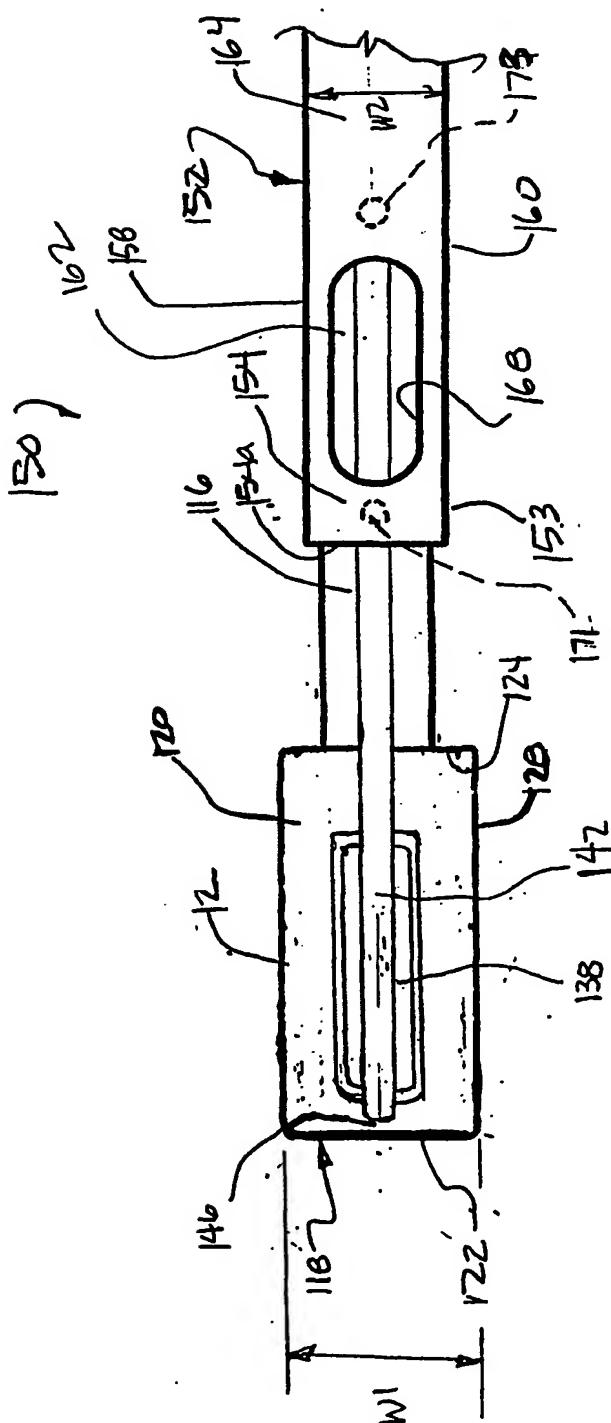
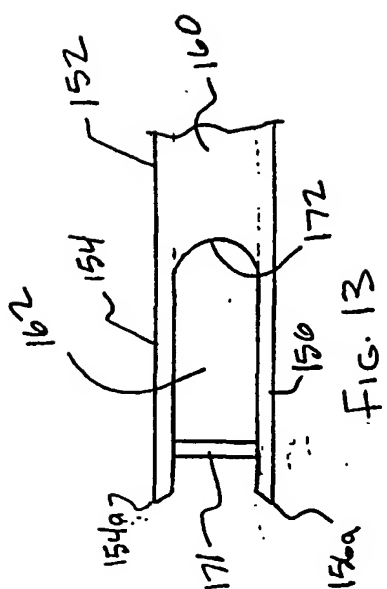


FIG. 1D





INTERNATIONAL SEARCH REPORT

In ternational Application No

PCT/US 01/42457

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 42269 A (HAIDER THOMAS T) 1 October 1998 (1998-10-01) abstract; figure 10 page 8, line 25-31	1,9,18
A	US 5 571 109 A (BERTAGNOLI RUDOLF) 5 November 1996 (1996-11-05) abstract; figures 1A,3	1,9,18
A	WO 99 52453 A (LIU MINGYAN ;SDGI HOLDINGS INC (US); BOYD LAWRENCE M (US); ESTES B) 21 October 1999 (1999-10-21) abstract; figures 5A,6	1,9,18
X	WO 98 17208 A (SURGICAL DYNAMICS INC) 30 April 1998 (1998-04-30) abstract; figure 24	16,30,35
A		1,9,18
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- *G* document member of the same patent family

Date of the actual completion of the international search

25 February 2002

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INTERNATIONAL SEARCH REPORT

In tional Application No

PCT/US 01/42457

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	<p>US 6 004 326 A (CASTRO SALVATORE ET AL) 21 December 1999 (1999-12-21) abstract; figure 1</p> <p>-----</p>	1,9,18

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/42457

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9842269	A	01-10-1998	WO 9842269 A1	01-10-1998
US 5571109	A	05-11-1996	DE 4328690 A1	02-03-1995
			AT 180157 T	15-06-1999
			CA 2129938 A1	27-02-1995
			DE 59408271 D1	24-06-1999
			EP 0641547 A2	08-03-1995
WO 9952453	A	21-10-1999	AU 739027 B2	04-10-2001
			AU 3488099 A	01-11-1999
			AU 3551899 A	01-11-1999
			AU 3744699 A	01-11-1999
			EP 1069862 A1	24-01-2001
			EP 1069864 A2	24-01-2001
			WO 9952446 A2	21-10-1999
			WO 9952447 A1	21-10-1999
			WO 9952453 A2	21-10-1999
			US 6241729 B1	05-06-2001
			US 6197033 B1	06-03-2001
			US 2001012942 A1	09-08-2001
WO 9817208	A	30-04-1998	US 5968098 A	19-10-1999
			US 6063088 A	16-05-2000
			AU 4991997 A	15-05-1998
			EP 1006955 A2	14-06-2000
			WO 9817208 A2	30-04-1998
US 6004326	A	21-12-1999	AU 9222098 A	29-03-1999
			EP 1011470 A1	28-06-2000
			JP 2001515749 T	25-09-2001
			WO 9912481 A1	18-03-1999

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(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
2 May 2002 (02.05.2002)

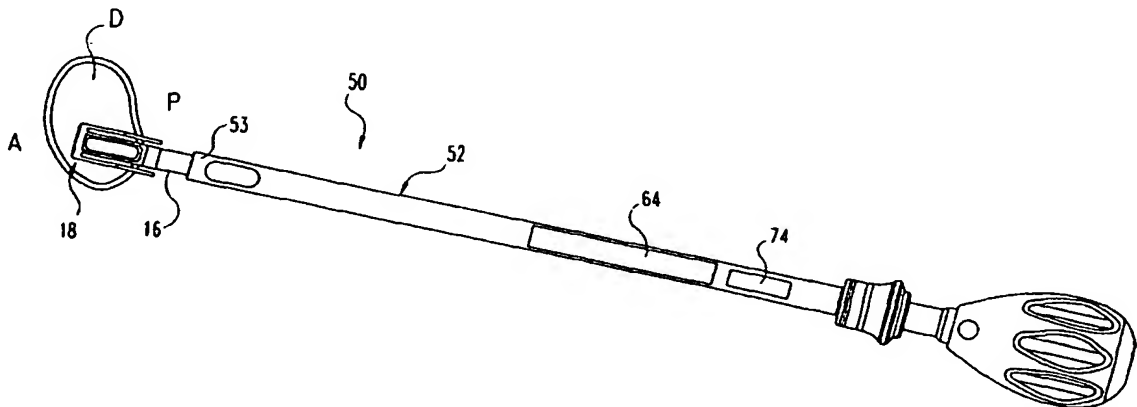
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09/692,980 **20 October 2000 (20.10.2000)** **US**
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- (72) Inventors; and
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- (74) Agents: **COLLIER, Douglas, A. et al.**; Woodard, Emhardt, Naughton, Moriarty & McNett, Bank One Center/Tower, Suite 3700, 111 Monument Circle, Indianapolis, IN 46204 (US).
- (81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).
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18 July 2002

[Continued on next page]

(54) Title: **METHODS AND INSTRUMENTS FOR INTERBODY SURGICAL TECHNIQUES**



(57) Abstract: This invention relates to methods and instruments for performing a surgical procedure in a disc space between adjacent vertebrae. The instruments include a distractor (18) and a cutting instrument (52). In one embodiment the distractor includes a body portion (20) and a pair of flanges (26, 28) extending along opposite sides of the body portion (20) such that a slot (42, 44) is formed between the flanges (26, 28) and the body portion (20). The cutting instrument (52) is positionable over the body portion (20) and into the slots (42, 44) of the distractor (18) so that the flanges (26, 28) are positioned between the cutting instrument (52) and the adjacent tissue.

WO 02/034144 A1



(15) Information about Correction:

see PCT Gazette No. 29/2002 of 18 July 2002, Section II

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

METHODS AND INSTRUMENTS FOR INTERBODY SURGICAL TECHNIQUES

5

Field of the Invention:

The present invention relates to spinal surgical techniques and instruments. More particularly, while aspects of the present invention may have other applications, the invention provides instruments and techniques suited for
10 interbody spinal surgery.

BACKGROUND OF THE INVENTION

Normally, intervertebral discs, which are located between endplates of adjacent vertebrae, stabilize the spine and distribute forces between the vertebrae
15 and cushion vertebral bodies. The discs may be displaced or damaged due to trauma, disease or aging. A herniated or ruptured annulus fibrosis may result in nerve damage, pain, numbness, muscle weakness, and even paralysis. Furthermore, as a result of the normal aging processes, discs dehydrate and harden, thereby reducing the disc space height and producing instability of the spine and
20 decreased mobility. Most typically surgical correction of a disc space includes a discectomy (surgical removal of a portion or the entire intervertebral disc.) The discectomy is often followed by preparation of the vertebral endplates to receive an implant, such as a fusion device. Fusion of the adjacent vertebrae is used to alleviate the pain associated with abnormal joint mechanics, premature
25 development of arthritis, and damage to the spinal structures.

Traditional surgical procedures for correction of spinal defects can cause significant trauma to the nerves and vasculature adjacent the spine. The potential for tissue trauma can be of particular concern when the surgical procedure dictates the use of a cutting instrument in the disc space in order to remove disc and bone
30 material to prepare the disc space for a fusion device, intervertebral spacer, or other

implant. In order to minimize the potential trauma, surgical procedures can require denervation and devascularization of tissue adjacent the disc space. Other procedures require manipulation of the nerves and vasculature in order to provide clear access to the disc space. While reducing the potential for contact with surgical instruments, manipulation and removal of the nerves and vasculature can still result in trauma and an increase the time and difficulty of the surgical procedure.

U.S. Patent No. 5,722,977 to Wilhelmy, incorporated herein by reference in its entirety, discloses a method and instrumentation for removal of a pair of rectangular blocks of vertebral bone tissue to provide an intervertebral recess. The instrumentation includes an intervertebral mortising cutter and a spacer that acts as a guide for the cutter. The procedure first requires the spacer to be inserted between the vertebral bodies. The cutter has a cutting head that defines a cavity that receives the spacer. In order to remove the bony material, the cutting head is pushed around the spacer and into the disc space. One disadvantage with the instrumentation disclosed in the '977 patent is that the cutting head is positioned between the spacer and the adjacent nerves and vasculature.

U.S. Patent No. 5,484,437 to Michelson discloses a technique and associated instrumentation for inserting a fusion device from a posterior surgical approach that provides protection for the surrounding tissues and neurological structures during the procedure. As described in more detail in the '437 patent, the surgical technique involves the use of a distractor having a penetrating portion that urges the vertebral bodies apart to facilitate the introduction of the necessary surgical instrumentation. The '437 patent also discloses a hollow sleeve having teeth at one end that are driven into the vertebrae adjacent the disc space created by the distractor. These teeth engage the vertebra to maintain the disc space height during subsequent steps of the procedure following removal of the distractor. In accordance with one aspect of the '437 patent, a drill is passed through the hollow sleeve to remove portions of the disc material and vertebral bone to produce a prepared bore for insertion of the fusion device. One disadvantage with this technique is that the procedure is performed through a sleeve, thus limiting working space and visibility of the surgeon. A further disadvantage is that the

height of the prepared disc space is limited by the spacing between penetrating portions of the distractor and the inner diameter of the sleeve.

While the more recent techniques and instrumentation represent an advance over earlier surgical procedures for the preparation of the disc space for insertion
5 of implants between the vertebrae, the need for improvement still remains. The present invention is directed to this need for improvement and provides convenient methods and instruments for safe and effective spinal surgical procedures.

SUMMARY OF THE INVENTION

The present invention is directed to a spinal disc space distractor having a pair of flanges that protect adjacent tissue from a cutting instrument. The present invention is also directed to a spinal instrument assembly for distracting and
5 cutting a disc space to prepare the disc space for insertion of one or more implants therein. The present invention is further directed to surgical methods and procedures using the distractor and spinal instrument assembly.

In accordance with one aspect of the invention, a distractor is provided. The distractor includes a body portion extending between a leading end and a
10 trailing end. The body portion has an upper surface and an opposite lower surface, and opposite first and second sidewalls extending between the upper and lower surfaces. A first flange and a second flange extend from the leading end of the body portion towards its trailing end. The first and second flanges are spaced a distance from a respective one of the first and second sidewalls.

15 In accordance with a further aspect of the invention, a distractor is provided that includes a body portion extending between a leading end and a trailing end. The body portion has an upper surface and an opposite lower surface, and opposite first and second sidewalls extending between the upper and lower surfaces. The body portion includes a cavity formed therein that extends between the upper and
20 lower surfaces.

In accordance with another aspect of the invention, a spinal instrument assembly for distracting and cutting the disc space between adjacent vertebrae is provided. The assembly includes a distractor and a cutter. The distractor includes a body portion extending between a leading end and a trailing end. The body
25 portion includes opposite first and second sidewalls extending between the adjacent vertebral bodies. The distractor also includes a first flange and a second flange extending from the leading end towards the trailing end of the body portion. Each of the first and second flanges forms a slot along the body portion with a respective one of the first and second sidewalls. An elongated stem extends
30 proximally from the trailing end of the body portion. The cutter includes a cutting head at the distal end of a shaft. An upper member, a lower member, and a pair of sidewalls extending therebetween form the shaft and cutting head. A channel

extends through the cutting head and shaft. The channel is sized to receive the stem of distractor and to receive the body portion of the distractor such that the distal end of the sidewalls of the cutter are positionable in the slot and the body portion of the distractor is received in the channel.

5 According to a further aspect of the invention, a distractor is provided with an interfitting cutter having a channel sized to receive the distractor. The cutter has width that is less than the width of the distractor.

10 According to another aspect of the invention, a method for preparing a disc space between adjacent vertebrae is provided. The method includes: accessing the disc space through the skin and tissue of a patient; inserting a distractor into the disc space, the distractor having a body portion extending between a leading end and a trailing end, the distractor further including a first flange and a second flange extending from the leading end towards the trailing end of the body portion, each of the first and second flanges forming a slot along the body portion; and
15 positioning a cutting head over the body portion and into the slots.

 Further embodiments, forms, aspects, objects, features, benefits and advantages of the present invention shall become apparent from the detailed drawings and descriptions provided herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top plan view of a distractor assembly according to one aspect of the present invention.

FIG. 2 is an enlarged top plan view of the distal end portion of the distractor assembly of FIG. 1 and the distal end portion of a cutter.

FIG. 3 is a side elevational view of the distal end portion of the distractor and cutter of FIG. 2.

FIG. 4 is a perspective view of a distractor-cutter assembly according to a further aspect of the present invention.

FIGS. 4(a) and 4(b) are sectional views taken through lines 4(a)-4(a) and 4(b)-4(b), respectively, of FIG. 4.

FIG. 5 is the perspective view of the distractor-cutter assembly of FIG. 4 with a handle attached the proximal end of the cutter.

FIG. 6 is a cross-sectional view of an alternate embodiment distractor according to the present invention.

FIG. 7 is a cross-sectional view of another alternate embodiment distractor according to the present invention.

FIG. 8 is a top plan view of the distractor assembly of FIG. 1 with the distractor inserted into a disc space from a generally posterior approach.

FIG. 9 is a top plan view of the distractor-cutter assembly of FIG. 5 with the distractor in the disc space and the cutter adjacent the disc space.

FIG. 10 is the distractor-cutter assembly of FIG. 5 with the distractor and the cutter in the disc space.

FIG. 11 is an enlarged view of the distal end portion of the distractor and cutter in the disc space.

FIG. 12 is an enlarged top plan view of the distal end portion of another embodiment distractor and cutter according to the present invention.

FIG. 13 is a side elevational view of the distal end portion of the cutter of FIG. 12.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the present invention, reference will now be made to the embodiments illustrated in the drawings, and specific language will be used to describe the same. It will
5 nevertheless be understood that no limitation of the scope of the invention is intended thereby. Any alterations and further modification in the described processes, systems, or devices, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

10 The instruments and methods of the present invention have application to a wide range of surgical procedures, and particularly spinal procedures for preparing a disc space for insertion of an implant into the disc space. It is further contemplated that the surgical instruments and methods of the present invention have application in open surgical procedures and in minimally invasive surgical
15 procedures.

Referring now to FIG. 1, a distractor assembly 10 insertable into the disc space between adjacent upper and lower vertebrae is provided. Distractor assembly 10 includes a handle 12 connected to a proximal end of a stem 16 via handle coupling 14. A distractor 18 is secured to a distal end of stem 16. It is
20 contemplated that distractor 18 can be permanently affixed or removably attached to stem 16.

Referring now further to FIG. 2, distractor 18 includes a body portion 20 extending between leading end 22 and trailing end 24. Distractor 18 has a pair of opposite outermost sidewalls that are formed by a first flange 26 and a second
25 flange 28 secured to body portion 20 at leading end 22. Flanges 26, 28 extend from leading end 22 towards trailing end 24. It is preferred that flanges 26, 28 are integrally formed with body portion 20 at leading end 22. In the illustrated embodiment, a first end wall 46 extends between leading end 22 and first flange 26 and a second end wall 48 extends between leading end 22 and second flange 28.
30 However, flanges 26, 28 could also be removably attached to body portion 20.

Body portion 20 has first sidewall 30 and an opposite second sidewall 32. As shown in FIG. 3, each of the sidewalls 30, 32 extend towards the adjacent

vertebrae between an upper surface 34 and a lower surface 36 of body portion 20. Referring back to FIG. 2, a first slot 42 is formed between first flange 26 and first sidewall 30. A second slot 44 is formed between second flange 28 and second sidewall 32. Slots 42 and 44 have a width "d" sized to accommodate the distal end
5 of a cutting instrument 52, as discussed further below.

Body portion 20 further includes a cavity 38 formed therethrough extending between upper surface 34 and lower surface 36. Body portion 20 has a height H1 between upper surface 34 and lower surface 36 that corresponds to the desired height for the distracted disc space. In the illustrated embodiment, the
10 leading end portion of body portion 20 tapers to a reduced height H2 between upper surface 34 and lower surface 36 at leading end 22 to facilitate insertion of distractor 18 into the disc space. Preferably, flanges 26, 28 have a height that is equal to or is less than height H1 of body portion 20, and have a tapered portion that corresponds to the taper of body portion 20 towards leading end 22. The depth
15 of insertion of distractor 18 into the disc space can be monitored under direct vision, with a viewing element inserted in the disc space, or via x-ray or fluoroscopic imaging of distractor 18.

Referring to FIGs. 2-5, according to a further aspect of the invention a cutting instrument or cutter 52 is provided that cooperates with and is interfittable
20 with distractor 18 to form a spinal instrument assembly 50. Spinal instrument assembly 50 provides for distraction of the adjacent vertebrae and for cutting material from the disc space and/or the adjacent vertebrae to form an implant insertion location. Cutter 52 includes a shaft 64 and a cutting head 53 at the distal end of shaft 64. Shaft 64 includes a first sidewall 58 and an opposite sidewall 60.
25 Sidewalls 58 and 60 are connected by an upper member 54 and an opposite lower member 56. Upper member 54 includes an upper cutting edge 54a at its distal end and lower member 56 includes a lower cutting edge 56a at its distal end. While the illustrated embodiment has shaft 64 with a square cross-sectional shape, other shapes are also contemplated, including, for example, a circular or rectangular
30 cross-section.

Shaft 64 includes an interior channel 62 formed therethrough that opens at the distal end of cutter 52. As shown in FIG. 4(a), channel 62 has a distal first

portion 62a sized to receive stem 16 and body portion 20 of distractor assembly 10 with handle 12 removed from stem 16. Preferably, first portion 62a has a size slightly larger than body portion 20 and a shape approximating the shape of body portion 20. This provides a slip fit between body portion 20 and cutting head 53
5 that will guide cutting head 53 into the disc space and into the bony material of the adjacent vertebral bodies. Although the cross-section of the remaining proximal portion of channel 62 can have any shape, it is contemplated that the entire length of channel 62 has a shape that corresponds to the shape of first portion 62a.

Distractor 18 has an overall width W1 between the first flange 26 and
10 second flange 28 that is greater the width W2 between the sidewalls 58, 60 of cutter 52. Distractor 18 thus ensures that when distractor 18 and cutter 52 are interfitted the flanges or outer-most sidewalls of distractor 18 are positioned adjacent the neural and vasculature tissue rather than the cutting edges of cutter 52.

In an alternate form shown in FIG. 4(b), channel 62 can be provided with a
15 proximal second portion 62b that has a size slightly larger than stem 16 and a cross-sectional shape that approximates the outer surface of stem 16. This minimizes the relative movement between stem 16 and cutter 52 as cutter 52 is slidably advanced along stem 16.

In one alternate embodiment shown in FIG. 6, distractor 18' has a body
20 portion 20' with a circular cross-sectional shape defined by first sidewall 30', opposite second sidewall 32', upper surface 34' and lower surface 36'. First flange 26' and second flange 28' each have a curved shape that parallels body portion 20', although vertically oriented flanges could also be provided. First slot 42' is formed between first flange 26' and sidewall 30' and second slot 44' is formed
25 between second flange 28' and sidewall 32'. In this embodiment, a cutter would be provided with a circular opening at its distal end and a cross-sectional shape that allows rotation, either manually or other known power means, about body portion 20' to cut the adjacent vertebral endplates. Flanges 26' and 28' protect the adjacent tissue from the rotating cutting head. Alternatively, a non-rotating cutter
30 could be used with distractor 18'.

In another alternate embodiment shown in FIG. 7, distractor 18'' has a first upper groove 21'' formed between upper surface 34'' and sidewall 30'' and a

second upper groove 23'' formed between upper surface 34'' and sidewall 32''. Distractor 18'' further has a first lower groove 25'' formed between lower surface 36'' and sidewall 30'' and a second lower groove 27'' formed between lower surface 36'' and sidewall 32''. The channel of cutter 52 can be configured to interfit with these grooves, thus allowing the grooves to guide the cutting edges of the cutter into the disc space. First slot 42'' is formed between first flange 26'' and sidewall 30'', and second slot 44'' is formed between second flange 28'' and sidewall 32''. Grooves 21'', 23'', 25'', and 27'' resist upward and downward movement of the cutting blades with respect to distractor 18'' while flanges 26'' and 28'' protect the adjacent tissue from the cutting blade.

Referring back to FIGs. 2-5, upper member 54 includes an opening 68 and lower member 56 includes an opening 70 (FIG. 4(a)) identical to opening 68. These openings are substantially alignable with cavity 38 of distractor 18, and facilitate the removal of cut material from cavity 38 when the instrument assembly is withdrawn from the disc space after cutting bony material. Cutter sidewall 60 includes a recess 72 formed therein, and cutter sidewall 58 includes a similarly shaped recess (not shown.) The recesses allow cutting edges 54a and 56a to be advanced beyond the leading end 22 of distractor 18. End walls 46, 48 prevent cutting head 53 from being advanced too far beyond leading end 22 of body portion 20.

Sidewall 60 includes a window 80 to further provide visual observation and/or confirmation of the position of cutting head 53 with respect to distractor 18 by enabling viewing of depth markings on stem 16 of distractor assembly 10. Shaft 64 further includes an imaging probe 74 adjacent its proximal end to provide image-guided control and monitoring of cutter 52. Further details regarding probe 74 are provided in U.S. Patent No. 6,021,343 to Foley et al., which is incorporated herein by reference in its entirety. Also contemplated are the use of x-ray and fluoroscopic imaging techniques to visualize cutting head 53 as it is inserted in the disc space.

Shaft 64 has a height H3 at its distal end that corresponds to the desired height of the prepared disc space into which the implant is to be inserted. It is contemplated that cutter 52 is inserted into the disc space with upper member 54

and lower member 56 parallel to the vertebral end plates and guided by body portion 20 of distractor 18. It is further contemplated that a number of cutters 52 of increasing height H3 may be provided and sequentially inserted over distractor 18 for removal of bony material from the vertebral endplates. While the illustrated cutter 52 has flat cutting edges 54a, 56a, other shapes for the cutting edges are also contemplated. For example, rounded upper and lower cutting edges could be used to cut an arched path in the vertebral endplates. A standard coupling 76 is provided at the proximal end of cutter 52 for attachment to a cutter handle 78 to facilitate gripping and control of cutter 52. The proximal end of cutter 52 can also be connected to or contacted by a driving tool, such as a slap hammer or the like to drive the cutting edges 54a, 56a into the bony material.

The steps of the spinal surgical procedure in accordance with one aspect of the present invention are depicted in FIGs. 8 – 11. In the depicted steps, there is illustrated a disc space D between adjacent vertebral bodies having a posterior side P and an anterior side A. The skin and tissue are excised and disc space D is accessed using any known surgical technique and instruments. Typically, an opening is made in the disc annulus at the desired entry location, and all or part of the disc nucleus can be excised through this annulus opening. As shown in FIG. 8, distractor 18 of distractor assembly 10 is inserted into disc space D to distract disc space to the desired height between the adjacent vertebrae. It is contemplated that, if necessary, the disc space can be sequentially distracted by known distractor instruments before insertion of distractor 18 or sequentially distracted by a number of distractors 18 of increasing height H1 until the desired disc space height is obtained.

When the desired distraction has been achieved, handle 12 is then removed from the proximal end of stem 16 and, as shown in FIG. 9, cutter 52 is slid over the proximal end of stem 16 to position cutting head 53 adjacent the disc space and distractor 18. As shown in FIGs. 10 and 11, cutter 52 is advanced over body portion 20 of distractor 18 so that the bony material of the vertebral endplates is cut by cutting edges 54a and 56a. At least a portion of the cut material is deposited in cavity 38 of distractor 18. Cutter 52 forms a path or track for implant insertion while distractor 18 maintains disc space distraction. Flanges 26, 28 protect the

adjacent vasculature and nerves, such as dura S and nerve root N, as cutter 52 is advanced over and interfitted with body portion 20.

When the implant insertion path is cut to the desired depth into the vertebral endplates, distractor assembly 10 and cutter 52 can be removed from disc space D. The material in cavity 38 can be removed through openings 68, 70 of cutter 52 to facilitate disassembly of the instruments. Further cleaning and debris removal in disc space D can be completed if necessary before one or more implants are inserted into the disc space. The inserted implant may be any device suitable for insertion into the disc space. In one specific form, it is contemplated that an implant is inserted in the disc space in order to restore the disc height, restore segmental alignment and balance, and immobilize the unstable degenerated intervertebral disc area. The implant(s) may be conveniently implanted with any known instruments and tools, and any instrument that will firmly hold the implant and permit insertion in the disc space is contemplated. In one specific form, the implant is a fusion device such as a bone dowel, push-in implant, threaded implant or the like, that is advanced into the site prepared with the instruments of the present invention at the subject disc space. The inserted implant provides support of the adjacent vertebrae, and can be packed with bone growth material to facilitate fusion. Graft material may also be placed directly in the prepared bore in the disc space, either without any implant or packed around the inserted implant.

It is also contemplated that more than one implant can be inserted at bilateral locations in the disc space through either a single lateral or transforaminal approach to the disc space, or through multiple approaches taken with an anterior or posterior mid-line approach to the disc space. The inserted implants provide bilateral support of the adjacent vertebrae, and can be packed with bone growth material to facilitate fusion.

The instruments and methods have been disclosed with reference to a particular application for disc space preparation and implant insertion from an oblique, posterior approach to the spine. However, it will be understood that the instruments and methods may be utilized, or modified for use, for a variety of surgical applications and approaches including, but not limited to, a unilateral posterior approach, a lateral approach, other oblique approaches, and an anterior

approach. The instruments also have applications with laparoscopic or endoscopic procedures on the spine, such as, through the working channel cannula/endoscope described in U.S. Patent Application No Appl. Ser. No. 09/160,882 filed September 15, 1998, which is incorporated herein by reference in its entirety.

5 Referring now further to FIGs. 12-13, an alternate embodiment spinal instrument assembly having a cutter guided by a distractor will be described. Assembly 150 includes a distractor 118 having a body portion 120 extending between leading end 122 and trailing end 124. Body 120 is attached to stem 116 at trailing end 124. Distractor 118 has a pair of opposite outermost sidewalls 126,
10 128 formed by body portion 120. In one form, a slot 142 extends from position adjacent leading end 122 proximally through body portion 120 and stem 116. Slot 142 preferably extends substantially along the longitudinal center axis of distractor 118. An end wall 146 is formed between leading end 122 and slot 142.

Body portion 120 further includes a cavity 138 formed therethrough
15 extending between the upper and lower surfaces of body portion 120. Body portion has a height between the upper and lower surface that corresponds to the desired height for the distracted disc space. The leading end portion of body portion 120 can be tapered as discussed above with respect to distractor 18.

A cutting instrument or cutter 152 is provided that cooperates and interfits
20 with distractor 118 to form spinal instrument assembly 150. Cutter 152 includes a shaft 164 and a cutting head 153 at the distal end of shaft 164. Shaft 164 includes a first sidewall 158 and an opposite sidewall 160. Sidewalls 158 and 160 are connected by an upper member 154 and an opposite lower member 156. Upper member 154 includes an upper cutting edge 154a at its distal end and lower
25 member 156 includes a lower cutting edge 156a at its distal end. Upper member 154 includes an opening 168 and lower member 156 includes an opening (not shown) that are substantially alignable with cavity 138 of distractor 118, and facilitate the removal of cut material from cavity 138. Cutter sidewall 160 includes a recess 172 formed therein, and cutter sidewall 158 includes a similarly shaped
30 recess (not shown.)

Shaft 164 includes an interior channel 162 formed therethrough that opens at the distal end of cutter 152. Channel 162 is sized to receive stem 116 and body

portion 120 of distractor 118. This provides a slip fit between body portion 120 and cutting head 153 that will guide cutting head 153 into the disc space and into the bony material of the adjacent vertebral bodies. The sidewall recesses are sized and shaped to receive body portion 120 of distractor 118 and allow cutting edges 154a and 156a to be advanced beyond the leading end 122 of distractor 118. End wall 146 prevents cutting head 153 from being advanced too far beyond leading end 122.

Where a slot 142 is provided in distractor 118, a first guide pin 171 and a second guide pin 173 are positioned in channel 162. Guide pins 171, 173 extend between and are secured to upper member 154 and lower member 156. Guide pins 171, 173 are slidably received in guide slot 142. Cutter 152 can be advanced over body portion 120 with body portion 120 positioned in channel 162 and received in and extending laterally outwardly from sidewall recesses 172. Guide pins 171, 173 positioned in guide slot 142 prevent lateral deviation of cutting head 153 with respect to body portion 120 as cutter 152 is advanced over distractor 118. Pins 171, 173 further act as braces that stabilize and strengthen shaft 164 in the area of the sidewall recesses.

Distractor 118 has an overall width W1 between the first sidewall 126 and second sidewall 128 that is greater the width W2 between the sidewalls 158, 160 of cutter 152. Guide slot 142 and pins 171, 173 and the interfitted arrangement between distractor 118 and cutter 152 ensure that the sidewalls of distractor 118 are positioned adjacent to the neural and vasculature tissue rather than the cutting edges of cutter 152.

While the invention has been illustrated and described in detail in the drawings and the foregoing description, the same is considered to be illustrative and not restrictive in character. It is understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A distractor, comprising:
a body portion extending between a leading end and a trailing end, said
body portion including an upper surface and an opposite lower surface and
5 opposite first and second sidewalls extending between said upper and lower
surfaces; and
a first flange and a second flange each extending proximally from said
leading end of said body portion towards said trailing end, said first flange spaced
a distance from said first sidewall and said second flange spaced a distance from
10 said second sidewall.
2. The distractor of claim 1, further comprising an elongated stem
extending proximally from said trailing end of said body portion.
- 15 3. The distractor of claim 2, further comprising a handle removably
attached to a proximal end of said stem.
4. The distractor of claim 1, wherein said body portion includes a
cavity formed therein, said cavity extending between said upper surface and said
20 lower surface.
5. The distractor of claim 1, wherein said distractor includes a first end
wall extending between said trailing end of said body portion and said first flange
and a second end wall extending between said trailing end of said body portion and
25 said second flange.
6. The distractor of claim 1, wherein said first and second flanges are
integrally formed with said leading end of said body portion.
- 30 7. The distractor of claim 1, wherein said body portion has a height
between said upper and lower surfaces, said height being tapered along a part of
the length of said body portion such that said height is reduced at said leading end.

8. The distractor of claim 7, wherein said first and second flanges each have a height corresponding to said height of said body portion.

5 9. A distractor for distracting the disc space between adjacent vertebral bodies, comprising:

a body portion extending between a leading end and a trailing end, said body portion including opposite first and second sidewalls extending between the adjacent vertebral bodies; and

10 a first flange and a second flange each extending from said leading end towards said trailing end of said body portion, each of said first and second flanges forming with a respective one of said first and second sidewalls a slot along said body portion.

15 10. The distractor of claim 9, wherein said body portion includes an upper surface and a lower surface, each of said upper and lower surfaces contactable with a respective endplate of one of the adjacent vertebrae.

20 11. The distractor of claim 10, wherein said body portion has a height between said upper and lower surfaces, said height being tapered along a part of the length of said body portion such that said height is reduced at said leading end.

25 12. The distractor of claim 11, wherein said first and second flanges each have a height corresponding to said height of said body portion.

13. The distractor of claim 9, further comprising an elongated stem extending from said trailing end of said body portion.

30 14. The distractor of claim 9, wherein said body portion includes a cavity formed therein, said cavity extending between said upper surface and said lower surface.

15. The distractor of claim 9, wherein said first and second flanges are integrally formed with said leading end of said body portion.

16. A distractor, comprising:

5 a body portion extending between a leading end and a trailing end, said body portion including an upper surface and an opposite lower surface and opposite first and second sidewalls extending between said upper and lower surfaces, at least a portion of said upper and lower surfaces being contactable with the endplates of adjacent vertebral bodies when said body portion is inserted in the
10 disc space between the adjacent vertebral bodies, wherein said body portion includes a cavity formed therein extending between said upper surface and said lower surface.

17. The distractor of claim 16, further comprising a first flange and a
15 second flange extending from said leading end of said body portion towards said trailing end of said body portion, each of said first and second flanges forming with a respective one of said first and second sidewalls a slot along said body portion.

18. A spinal instrument assembly, comprising:

20 a distractor including:

a body portion extending between a leading end and a trailing end, said body portion including opposite first and second sidewalls extending between the adjacent vertebral bodies;

25 a first flange and a second flange each extending from said leading end towards said trailing end of said body portion, each of said first and second flanges forming with a respective one of said first and second sidewalls a slot along said body portion;

an elongated stem extending proximally from said trailing end of said body portion; and

30 a cutting instrument including:

an elongated shaft having a distal cutting end, said shaft including an upper member, a lower member, and a pair of sidewalls extending

therebetween, said shaft defining a channel sized to receive said body portion of said distractor whereby said sidewalls are positionable in a respective one of said slots when said body portion of said distractor is in said channel of said shaft.

5 19. The assembly of claim 18, wherein each of said sidewalls of said shaft include a proximally extending recess formed therein at the distal end of said sidewall.

 20. The assembly of claim 18, wherein:
10 said upper member includes a cutting edge formed at the distal end of said upper member; and
 said lower member includes a cutting edge formed at the distal end of said lower member.

15 21. The assembly of claim 18, wherein:
 said body portion of said distractor includes a cavity formed therethrough extending between an upper surface and a lower surface of said body portion; and
 said upper member and said lower member of said shaft each define an opening therethrough in communication with said channel and alignable with said
20 cavity.

 22. The assembly of claim 18, wherein said distractor includes a first end wall extending between said leading end of said body portion and said first flange and a second end wall extending between said leading end of said body
25 portion and said second flange.

 23. The assembly of claim 18, wherein said shaft includes a probe for image guided navigation of said cutting head.

30 24. The assembly of claim 23, wherein said shaft includes a coupling member at a proximal end of said shaft for attachment of a handle thereto.

25. The assembly of claim 18, wherein at least one of said sidewalls of said shaft defines a window in communication with said channel.

5 26. A method for preparing a disc space between adjacent vertebrae, comprising:

accessing the disc space through the skin and tissue of a patient;

inserting a distractor into the disc space, the distractor having a body portion extending between a leading end and a trailing end, the distractor further
10 including a first flange and a second flange extending from said leading end towards said trailing end of said body portion, each of said first and second flanges forming a slot along said body portion; and

positioning a cutter over the body portion and into the slots formed between the body portion and the first and second flanges of the distractor.

15

27. The method according to claim 26, wherein positioning the cutter includes cutting bony material from the adjacent vertebral endplates to form an implant insertion location in the disc space.

20 28. The method according to claim 27, further comprising depositing at least a portion of the cut bony material into a cavity formed in the body portion of the distractor.

29. The method according to claim 27, further comprising inserting an
25 implant in the implant insertion location.

30. A spinal instrument assembly, comprising:

a distractor including a body portion extending between a leading end and a trailing end, said body portion including opposite first and second sidewalls
30 extending between the adjacent vertebral bodies and having a first width between said sidewalls;

a cutting instrument including an elongated shaft having a distal cutting end, said distal cutting end of said shaft configured to interfit with said distractor and having a channel with a height sized to receive said body portion of said distractor, said distal cutting end having a second width that is less than said first
5 width.

31. The assembly of claim 30, wherein said distractor includes:
a first flange and a second flange each extending from said leading end towards said trailing end of said body portion, each of said first and second flanges
10 forming with a respective one of said first and second body portion sidewalls a slot along said body portion; and
an elongated stem extending proximally from said trailing end of said body portion.

15 32. The assembly of claim 31, whereby said distal cutting end of said cutting instrument is positionable in a respective one of said slots when said body portion of said distractor is in said channel of said shaft.

20 33. The assembly of claim 32, wherein said distractor includes a first end wall extending between said leading end of said body portion and said first flange and a second end wall extending between said leading end of said body portion and said second flange.

25 34. The assembly of claim 30, wherein said distal cutting end includes opposite proximally extending recesses sized to receive said body portion of said distractor.

30 35. The assembly of claim 30, wherein said distal cutting end includes an upper member having a cutting edge formed at the distal end of said upper member and a lower member including a cutting edge formed at the distal end of said lower member.

36. The assembly of claim 30, wherein:

said body portion of said distractor includes a cavity formed therethrough
extending between an upper surface and a lower surface of said body portion; and
said shaft defines an opening therethrough in communication with said
5 channel and alignable with said cavity.

37. The assembly of claim 30, wherein:

said body portion of said distractor includes a guide slot formed
therethrough extending generally parallel with said sidewalls of said body portion;
10 and

said cutting instrument includes at least one guide pin in said channel of
said shaft, wherein said guide pin is slidably received in said guide slot.

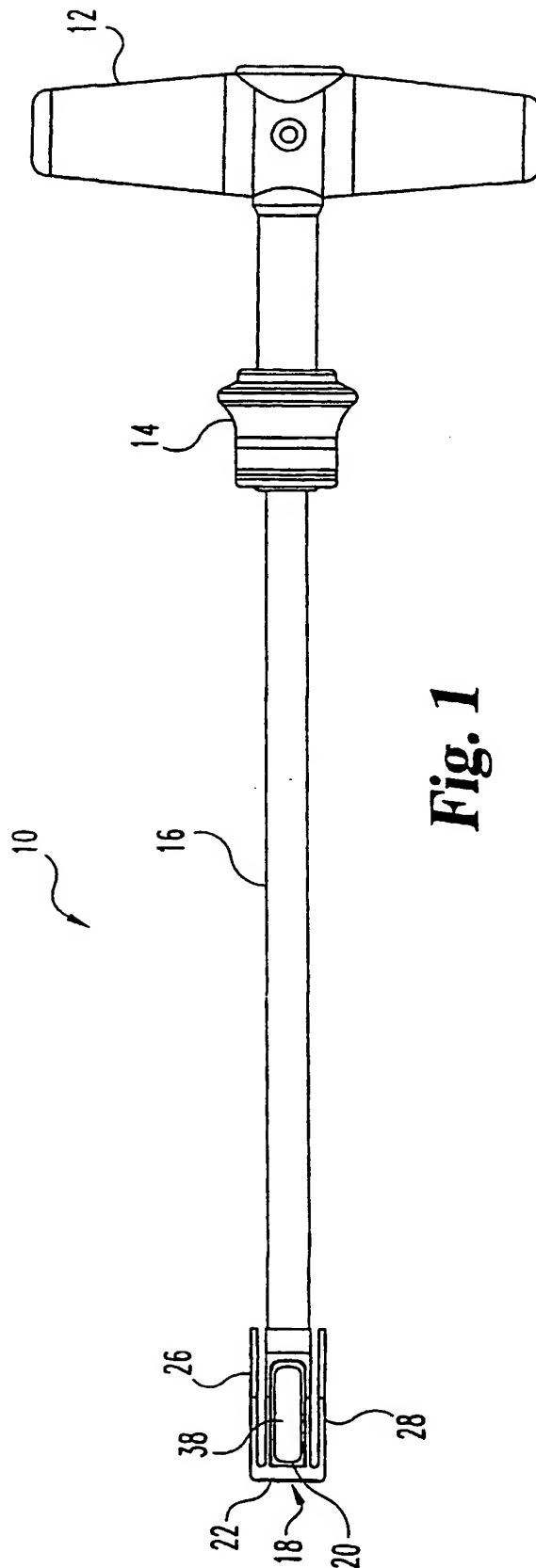


Fig. 1

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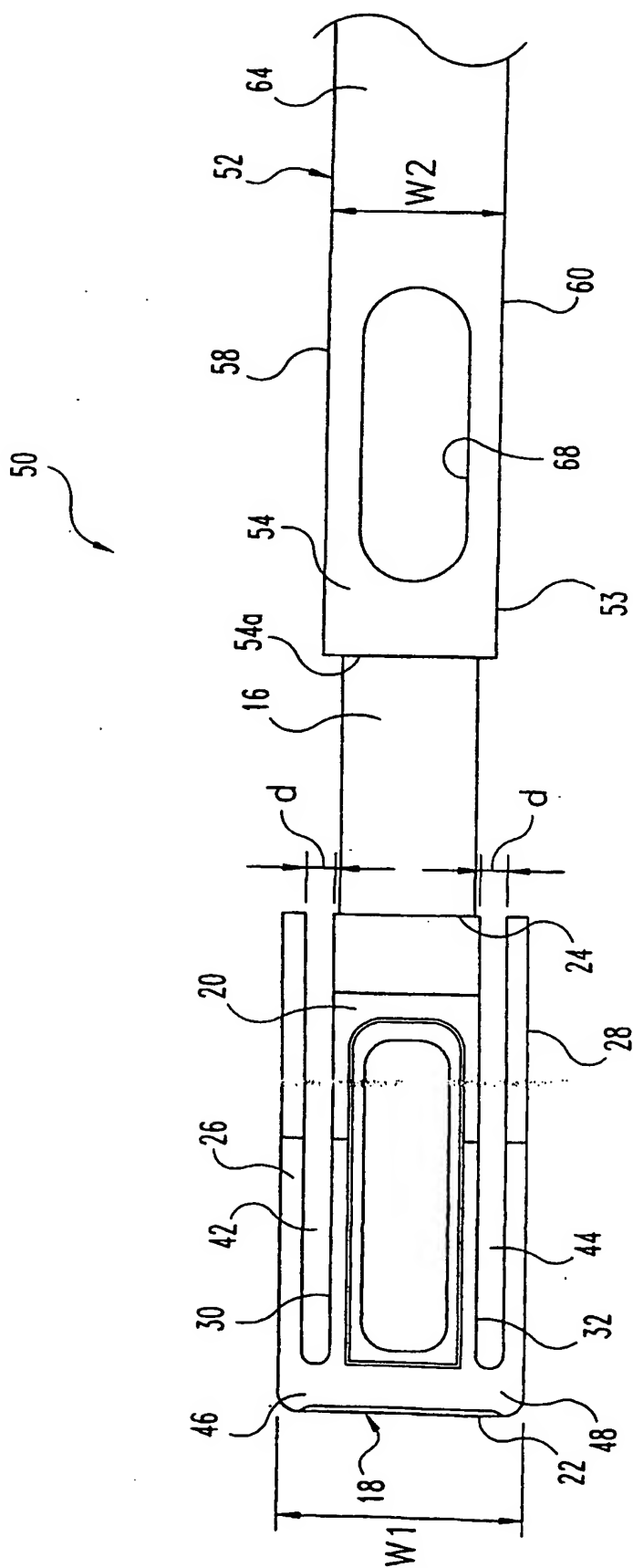


Fig. 2

SUBSTITUTE SHEET (RULE 26)

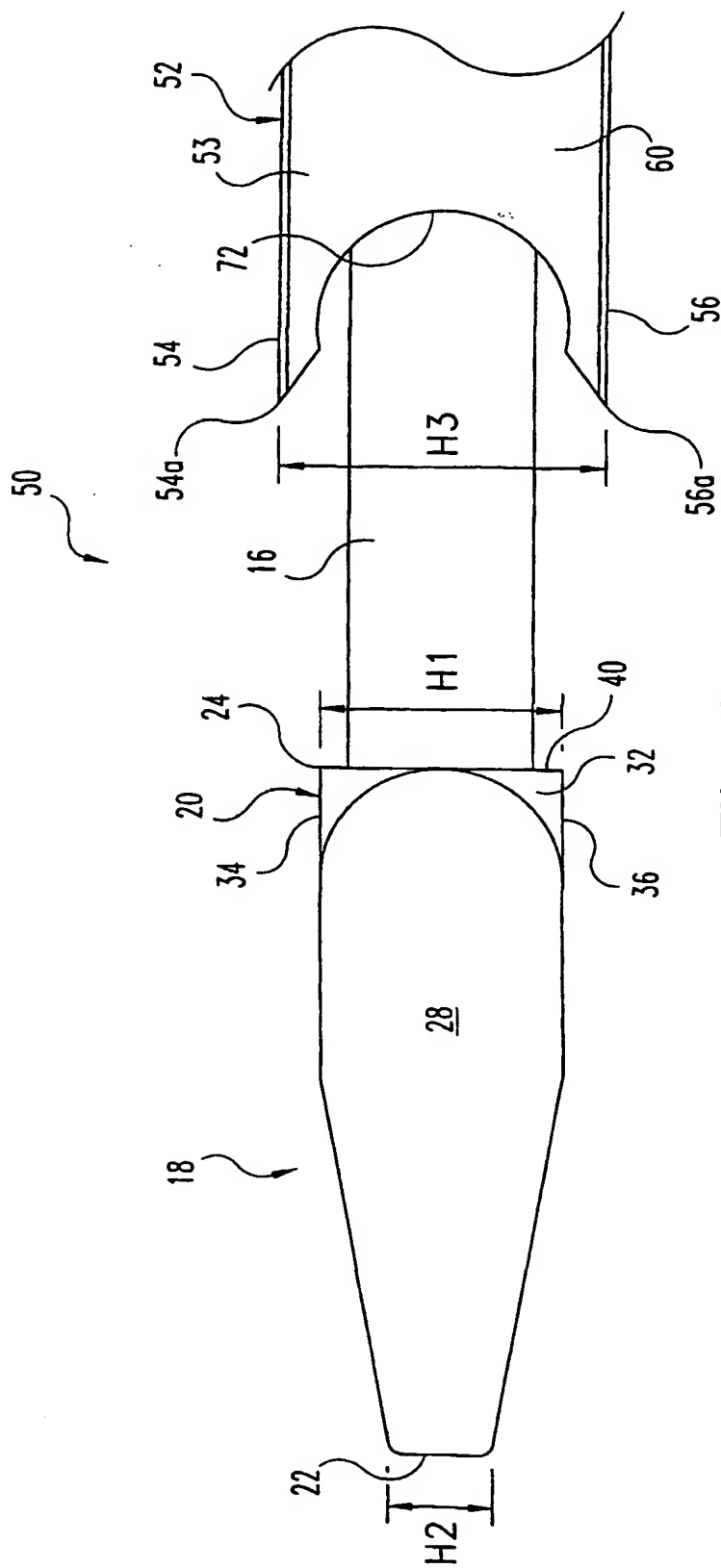


Fig. 3

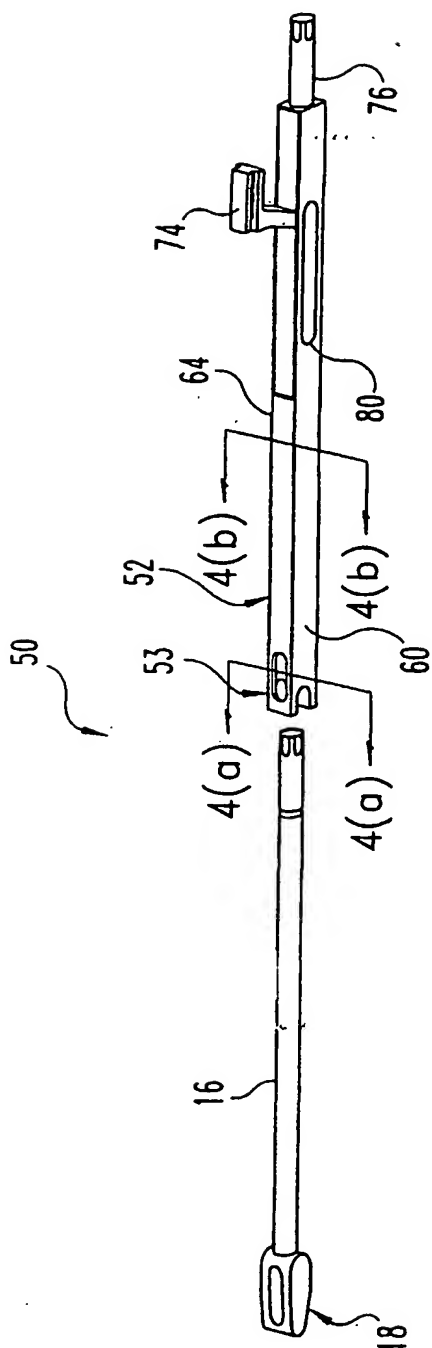


Fig. 4

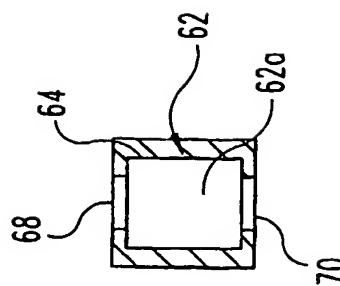


Fig. 4(a)

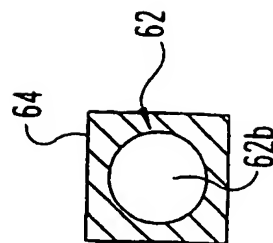


Fig. 4(b)

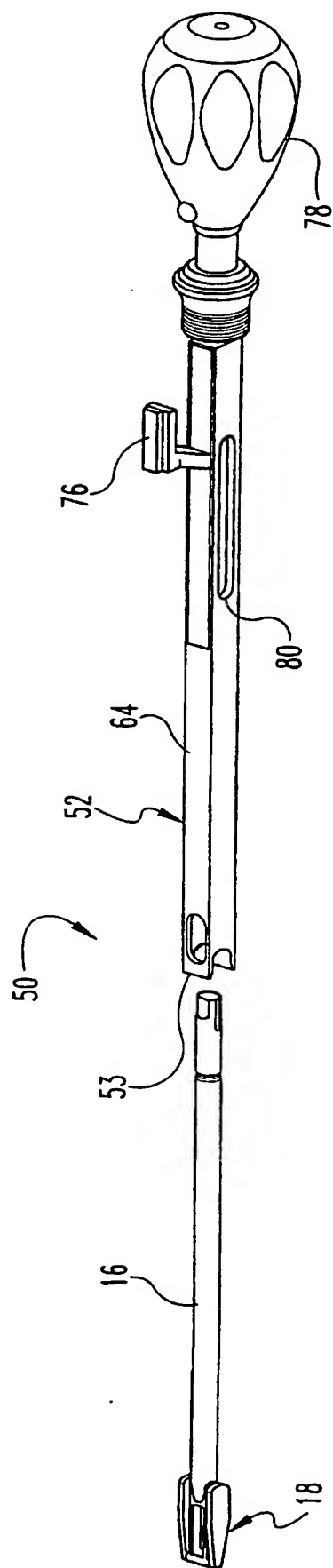


Fig. 5

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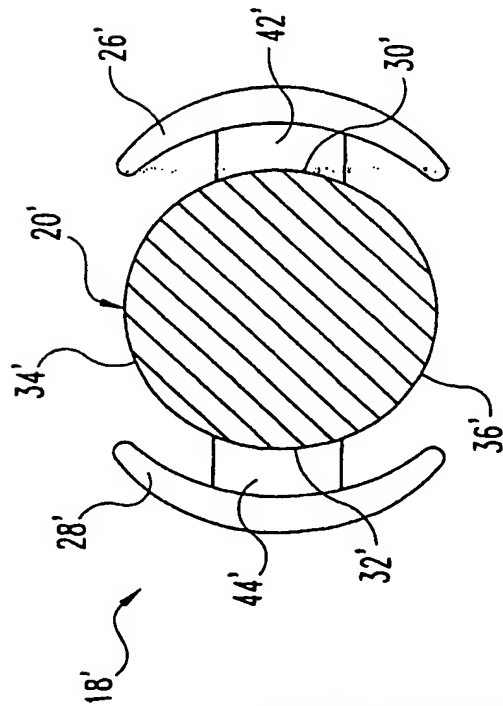


Fig. 6

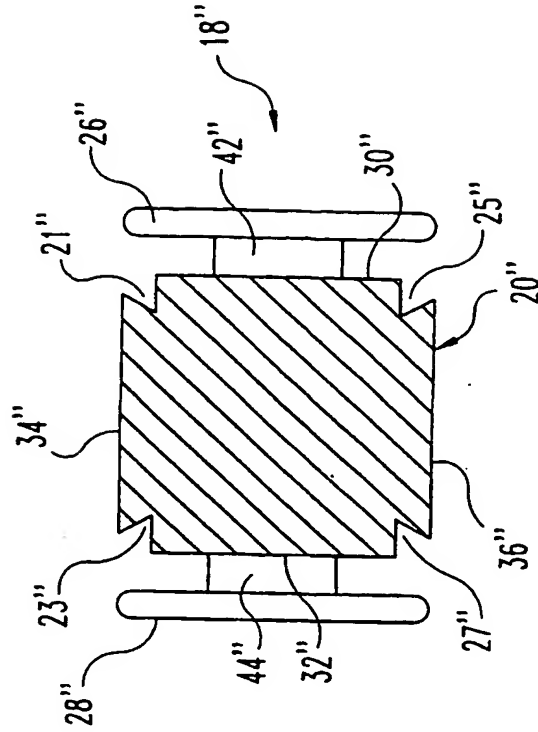


Fig. 7

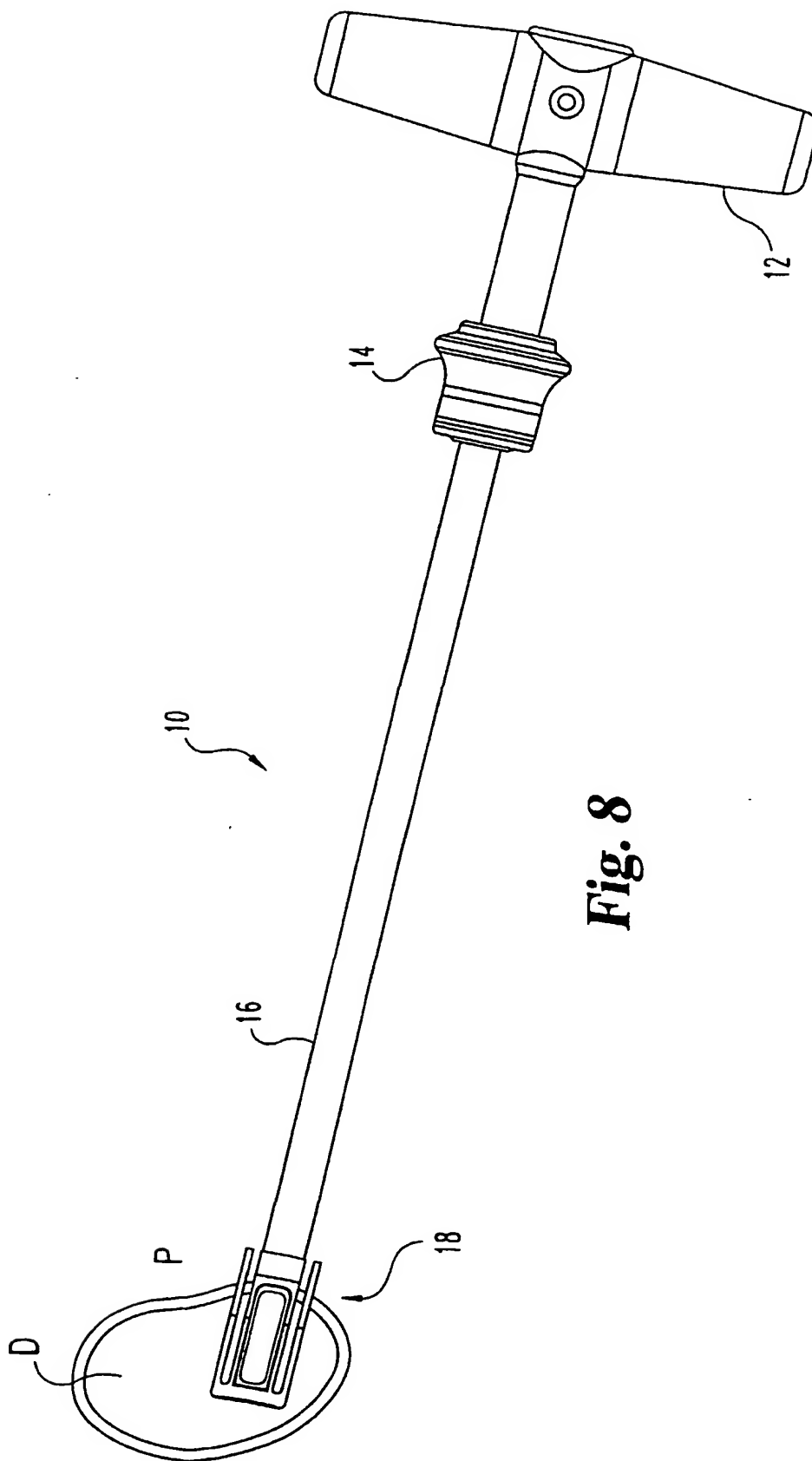


Fig. 8

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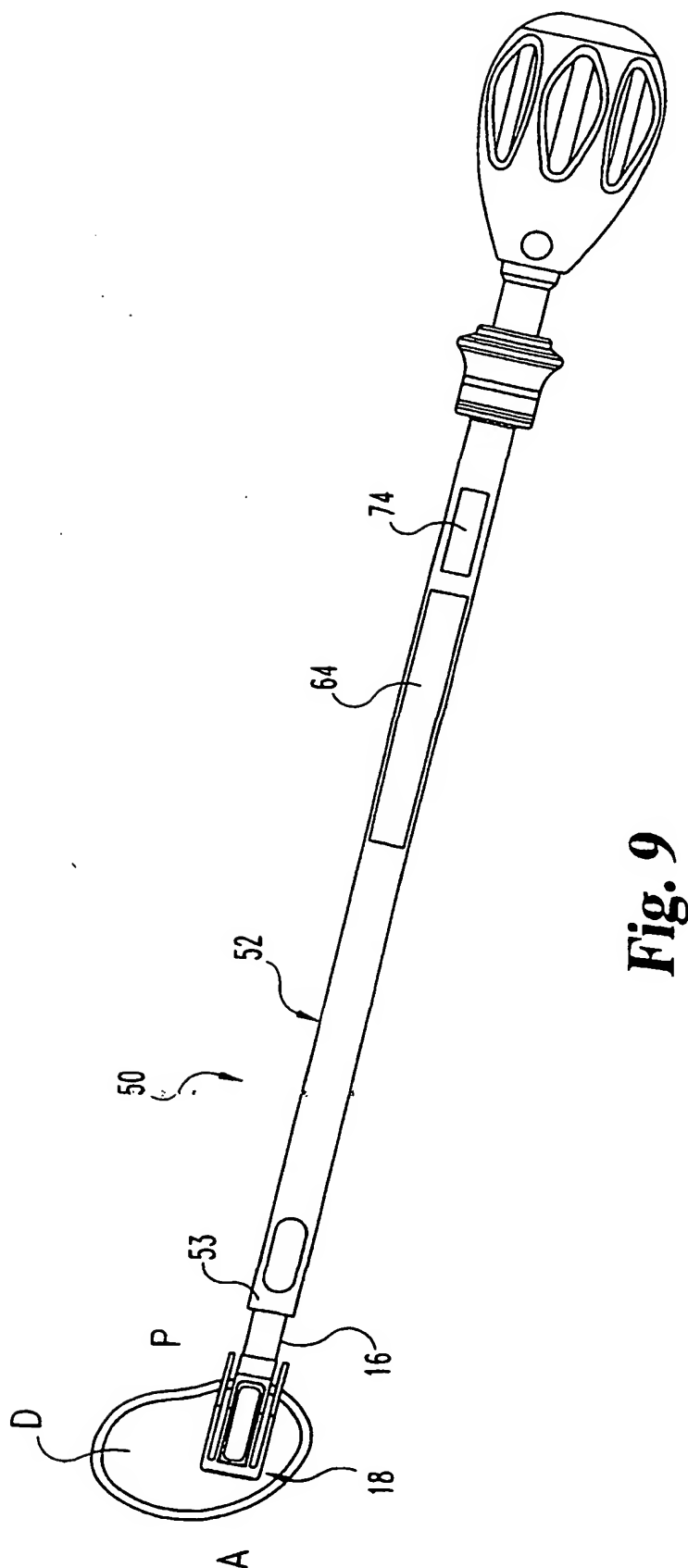


Fig. 9

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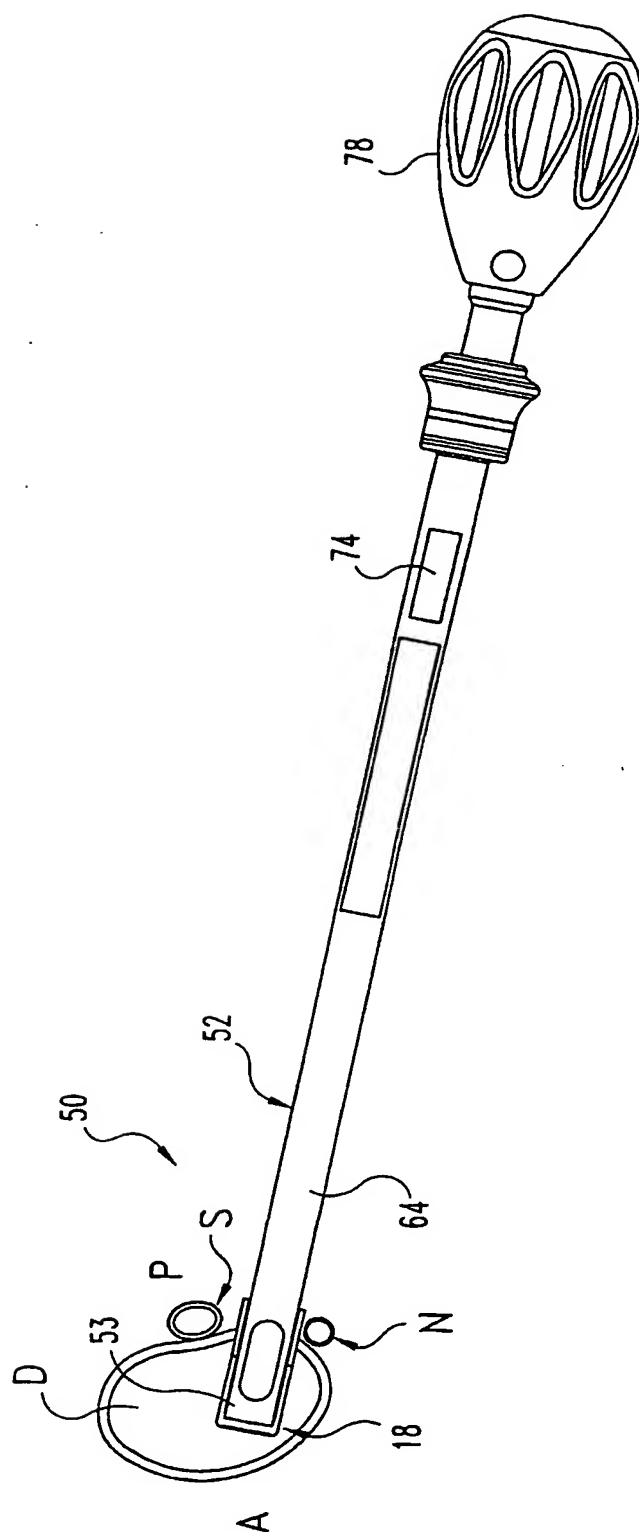


Fig. 10

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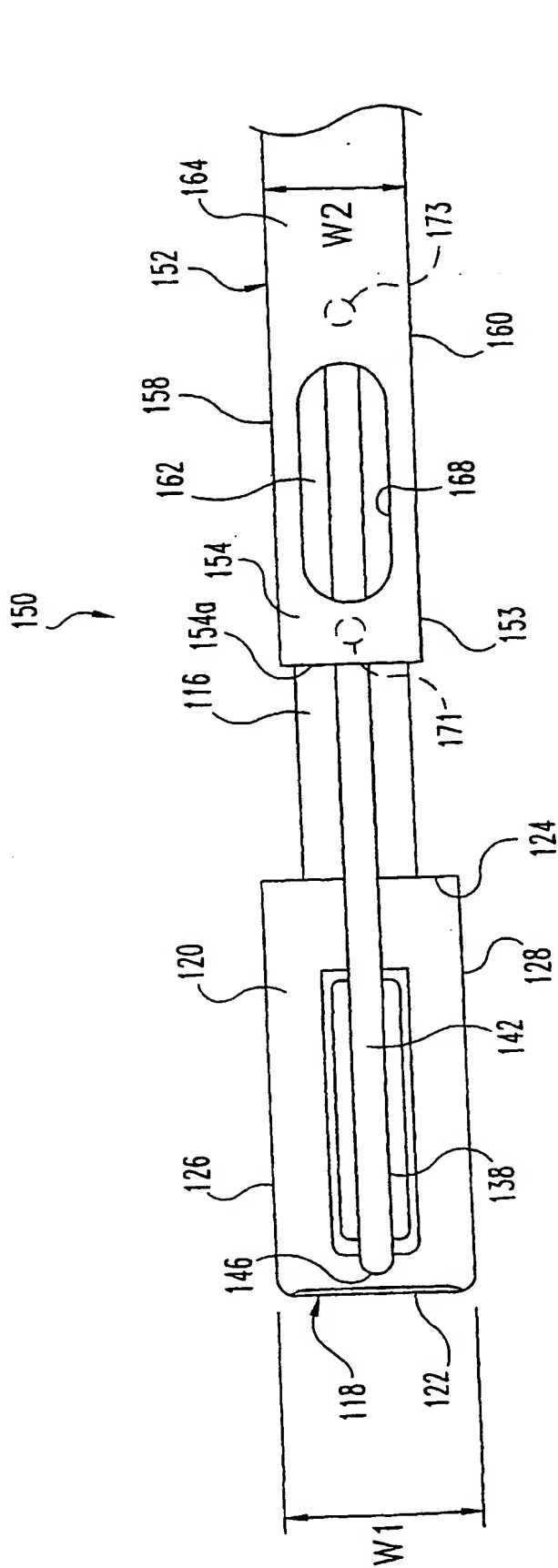


Fig. 12

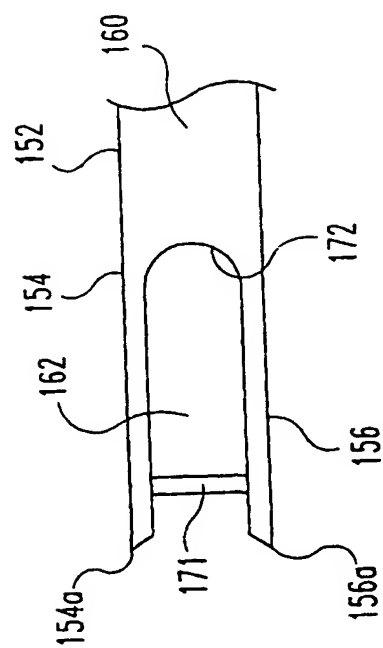


Fig. 13

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/42457

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B17/16

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 98 42269 A (HAIDER THOMAS T) 1 October 1998 (1998-10-01) abstract; figure 10 page 8, line 25-31	1,9,18
A	US 5 571 109 A (BERTAGNOLI RUDOLF) 5 November 1996 (1996-11-05) abstract; figures 1A,3	1,9,18
A	WO 99 52453 A (LIU MINGYAN ;SDGI HOLDINGS INC (US); BOYD LAWRENCE M (US); ESTES B) 21 October 1999 (1999-10-21) abstract; figures 5A,6	1,9,18
X	WO 98 17208 A (SURGICAL DYNAMICS INC) 30 April 1998 (1998-04-30)	16,30,35
A	abstract; figure 24 -- -/-	1,9,18

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
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- *O* document referring to an oral disclosure, use, exhibition or other means
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- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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- *G* document member of the same patent family

Date of the actual completion of the international search

25 February 2002

Date of mailing of the international search report

05/03/2002

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INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 01/42457

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 6 004 326 A (CASTRO SALVATORE ET AL) 21 December 1999 (1999-12-21) abstract; figure 1	1,9,18

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

In International Application No

PCT/US 01/42457

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9842269	A	01-10-1998	WO 9842269 A1	01-10-1998
US 5571109	A	05-11-1996	DE 4328690 A1	02-03-1995
			AT 180157 T	15-06-1999
			CA 2129938 A1	27-02-1995
			DE 59408271 D1	24-06-1999
			EP 0641547 A2	08-03-1995
WO 9952453	A	21-10-1999	AU 739027 B2	04-10-2001
			AU 3488099 A	01-11-1999
			AU 3551899 A	01-11-1999
			AU 3744699 A	01-11-1999
			EP 1069862 A1	24-01-2001
			EP 1069864 A2	24-01-2001
			WO 9952446 A2	21-10-1999
			WO 9952447 A1	21-10-1999
			WO 9952453 A2	21-10-1999
			US 6241729 B1	05-06-2001
			US 6197033 B1	06-03-2001
			US 2001012942 A1	09-08-2001
WO 9817208	A	30-04-1998	US 5968098 A	19-10-1999
			US 6063088 A	16-05-2000
			AU 4991997 A	15-05-1998
			EP 1006955 A2	14-06-2000
			WO 9817208 A2	30-04-1998
US 6004326	A	21-12-1999	AU 9222098 A	29-03-1999
			EP 1011470 A1	28-06-2000
			JP 2001515749 T	25-09-2001
			WO 9912481 A1	18-03-1999

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